

**MAGNETICALLY SHIELDED ASSEMBLY**

**Cross-reference to related patent application**

This patent application is a continuation-in-part of applicants' copending patent application U.S.S.N. 10/366,082, filed on February 13, 2003, which in turn was a continuation-in-part of applicants' copending patent application 10/324,773, filed on December 18, 2002. The entire disclosure of each of these United States patent applications is hereby incorporated by reference into this specification.

This patent application is also a continuation-in-part of applicants' copending patent applications U.S.S.N. 10/090,553, filed on March 4, 2002, U.S.S.N. 10/229,183, filed on August 26, 2002, U.S.S.N. 10/242,969, filed on September 13, 2002, U.S.S.N. 10/260,247, filed on September 30, 2002, U.S.S.N. 10/273,738, filed on October 18, 2002, U.S.S.N. 10/303,264, filed on November 25, 2002, and U.S.S.N. 10/313,847, filed on December 7, 2002. The entire disclosure of each of these United States patent applications is hereby incorporated by reference into this specification.

**Field of the invention**

A magnetically shielded assembly comprising a implanted medical device contiguous with biological tissue, wherein the device is comprised of coating containing nanomagnetic particles disposed within an insulating matrix and bonded to a substrate. . The coating has a morphological density of at least about 98 percent.

**Background of the invention**

Applicants' United States patent 6,502,972 describes and claims a magnetically shielded conductor assembly comprised of a first conductor disposed within an insulating matrix, and a layer comprised of nanomagnetic material disposed around said first conductor, provided that such nanomagnetic material is not contiguous with said first conductor. In this assembly, the first conductor has a resistivity at 20 degrees Centigrade of from about 1 to about 100 micro ohm-centimeters, the insulating matrix is comprised of nano-sized particles wherein at least about 90 weight percent of said particles have a maximum dimension of from about 10 to about 100 nanometers, the insulating matrix has a resistivity of from about 1,000,000,000 to about 10,000,000,000,000 ohm-centimeter, the nanomagnetic material has an average particle size of less than about 100 nanometers, the layer of nanomagnetic material has a saturation magnetization of from about 200 to about 26,000 Gauss and a thickness of less than about 2 microns, and the magnetically shielded conductor assembly is flexible, having a bend radius of less than 2 centimeters. The entire disclosure of this United States patent is hereby incorporated by reference into this specification.

The nanomagnetic film disclosed in United States patent 6,506,972 may be used to shield implanted medical devices from external electromagnetic fields; and, when so used, it provides a certain degree of shielding.

It is an object of this invention to provide an improved nanomagnetic coating.

#### Summary of the invention

In accordance with this invention, there is provided a magnetically shielded assembly comprising a implanted medical device contiguous with biological tissue, wherein the magnetically shielded assembly is comprised of a magnetically shielded

substrate disposed over said implanted medical device. The magnetically shielded substrate comprises a coating with a morphological density of at least about 98 percent bonded to such substrate.

Brief description of the drawings

The present invention will be more fully understood by reference to the following detailed thereof, when read in conjunction with the attached drawings, wherein like reference numerals refer to like elements, and wherein:

Figure 1 is a schematic illustration of one preferred embodiment of the process of the invention;

Figure 2 is a schematic illustration of another preferred embodiment of the process of the invention;

Figure 3 is a phase diagram of a preferred nanomagnetic material;

Figure 4 is a schematic of the spacing between components of the nanomagnetic material of Figure 3;

Figures 5 is a schematic representation of a magnetic shield;

Figure 6A through 6E are schematics of several preferred magnetically shielded assemblies;

Figure 7 is a schematic of a circuit for cooling a substrate that is subjected to electromagnetic radiation;

Figure 8 is a schematic illustration of one preferred assembly for shielding cardiac tissue from the adverse effects of electromagnetic radiation;

Figure 9 is a flow diagram of a preferred process for shielding biological tissue from electromagnetic radiation;

Figure 10 is a schematic diagram illustrating a preferred sputtering process for making one magnetically shielded assembly of the invention;

Figures 11 and 11A are partial schematic views of a stent coated with a film made by the process of the invention;

Figure 12 is a schematic view of the stent of Figure 11 illustrating how it responds to the electromagnetic radiation present in a magnetic resonance imaging (MRI) field;

Figures 13, 14, and 15 are graphs illustrating how the stent of Figure 13, the coating of the stent of Figure 13, and the coated stent of Figure 13 react to the electromagnetic radiation present in an MRI field in terms their magnetizations, their reactances, and their image clarities;

Figure 16 is a schematic illustration of a cylindrical coated substrate;

Figures 17A, 17B, and 17C are schematic views of a coated catheter assembly;

Figures 18A, 18B, 18C, 18D, 18E, 18F, and 18G are schematic views of a coated catheter assembly comprised of multiple concentric elements;

Figures 19A, 19B, and 19C are schematic views of a coated guide wire assembly;

Figures 20A and 20B are schematic views of a coated medical stent assembly;

Figure 21 is a schematic view of a coated biopsy probe assembly;

Figures 22A and 22B are schematic views of a coated flexible tube endoscope tube assembly;

Figure 23A is a schematic view of a sheath assembly;

Figure 23B is a schematic illustration of a process for making the sheath assembly of Figure 23A;

Figure 24 is a phase diagram illustrating certain preferred compositions of the invention;

Figure 25 is a schematic view of a coated substrate comprised of nanoelectrical particles;

Figure 26 is a schematic view of a sensor assembly;

Figures 27A and 27B are illustrations of a sputtering process for making doped aluminum nitride

Figure 28 is a schematic representation of a film orientation <002> of aluminum nitride;

Figure 29 is a schematic illustration of a preferred sputtering process;

Figures 30 and 31 are schematic illustrations of an aluminum nitride construct;

Figures 32A and 32B are sectional and top views, respectively, of a coated substrate assembly whose coating has a morphological density of at least about 98 percent;

Figures 33A, 33B, and 33C illustrate the MRI images obtained with several of the coated constructs of this invention;

Figure 34A illustrates a coated substrate comprised of a hydrophobic coating;

Figure 34B illustrates a coated substrate comprised of a hydrophilic coating; and

Figure 35 is a schematic illustration of a coating bonded to a substrate through an interfacial layer disposed between the coating and the substrate.

Description of the preferred embodiments

Figure 1 is a schematic illustration of one process of the invention which may be used to make nanomagnetic material. This Figure 1 is similar in many respects to the Figure 1 of United States patent 5,213,851, the entire disclosure of which is hereby incorporated by reference into this specification.

Referring to Figure 1, and in the preferred embodiment depicted therein, it is preferred that the reagents charged into misting chamber 12 will be sufficient to form a nano-sized ferrite in the process. The term ferrite, as used in this specification, refers to a material that exhibits ferromagnetism. Ferromagnetism is a property, exhibited by certain metals, alloys, and compounds of the transition (iron group) rare earth and actinide elements, in which the internal magnetic moments spontaneously organize in a common direction; ferromagnetism gives rise to a permeability considerably greater than that of vacuum and to magnetic hysteresis. See, e.g., page 706 of Sybil B. Parker's "McGraw-Hill Dictionary of Scientific and Technical Terms," Fourth Edition (McGraw-Hill Book Company, New York, New York, 1989).

As will be apparent to those skilled in the art, in addition to making nano-sized ferrites by the process depicted in Figure 1, one may also make other nano-sized materials such as, e.g., nano-sized nitrides and/or nano-sized oxides containing moieties A, B, and C (see Figure 3 and its accompanying discussion).

Referring again to Figure 1, and to the production of ferrites by such process, in one embodiment, the ferromagnetic material contains  $\text{Fe}_2\text{O}_3$ . See, for example, United

States patent 3,576,672 of Harris et al., the entire disclosure of which is hereby incorporated by reference into this specification. As will be apparent, the corresponding nitrides also may be made.

In one embodiment, the ferromagnetic material contains garnet. Pure iron garnet has the formula  $M_3Fe_5O_{12}$ ; see, e.g., pages 65-256 of Wilhelm H. Von Aulock's "Handbook of Microwave Ferrite Materials" (Academic Press, New York, 1965). Garnet ferrites are also described, e.g., in United States patent 4,721,547, the disclosure of which is hereby incorporated by reference into this specification. As will be apparent, the corresponding nitrides also may be made.

In another embodiment, the ferromagnetic material contains a spinel ferrite. Spinel ferrites usually have the formula  $MFe_2O_4$ , wherein M is a divalent metal ion and Fe is a trivalent iron ion. M is typically selected from the group consisting of nickel, zinc, magnesium, manganese, and like. These spinel ferrites are well known and are described, for example, in United States patents 5,001,014, 5,000,909, 4,966,625, 4,960,582, 4,957,812, 4,880,599, 4,862,117, 4,855,205, 4,680,130, 4,490,268, 3,822,210, 3,635,898, 3,542,685, 3,421,933, and the like. The disclosure of each of these patents is hereby incorporated by reference into this specification. Reference may also be had to pages 269-406 of the Von Aulock book for a discussion of spinel ferrites. As will be apparent, the corresponding nitrides also may be made.

In yet another embodiment, the ferromagnetic material contains a lithium ferrite. Lithium ferrites are often described by the formula  $(Li_{0.5}Fe_{0.5})_2 + (Fe_2)3 + O_4$ . Some illustrative lithium ferrites are described on pages 407-434 of the aforementioned Von Aulock book and in United States patents 4,277,356, 4,238,342, 4,177,438, 4,155,963,

4,093,781, 4,067,922, 3,998,757, 3,767,581, 3,640,867, and the like. The disclosure of each of these patents is hereby incorporated by reference into this specification. As will be apparent, the corresponding nitrides also may be made.

In yet another embodiment, the ferromagnetic material contains a hexagonal ferrite. These ferrites are well known and are disclosed on pages 451-518 of the Von Aulock book and also in United States patents 4,816,292, 4,189,521, 5,061,586, 5,055,322, 5,051,201, 5,047,290, 5,036,629, 5,034,243, 5,032,931, and the like. The disclosure of each of these patents is hereby incorporated by reference into this specification. As will be apparent, the corresponding nitrides also may be made.

In yet another embodiment, the ferromagnetic material contains one or more of the moieties A, B, and C disclosed in the phase diagram of Figure 3 and discussed elsewhere in this specification.

Referring again to Figure 1, and in the preferred embodiment depicted therein, it will be appreciated that the solution 10 will preferably comprise reagents necessary to form the required magnetic material. For example, in one embodiment, in order to form the spinel nickel ferrite of the formula  $\text{NiFe}_2\text{O}_4$ , the solution should contain nickel and iron, which may be present in the form of nickel nitrate and iron nitrate. By way of further example, one may use nickel chloride and iron chloride to form the same spinel. By way of further example, one may use nickel sulfate and iron sulfate.

It will be apparent to skilled chemists that many other combinations of reagents, both stoichiometric and nonstoichiometric, may be used in applicants' process to make many different magnetic materials.

In one preferred embodiment, the solution 10 contains the reagent needed to produce a desired ferrite in stoichiometric ratio. Thus, to make the  $\text{NiFe}_2\text{O}_4$  ferrite in this embodiment, one mole of nickel nitrate may be charged with every two moles of iron nitrate.

In one embodiment, the starting materials are powders with purities exceeding 99 percent.

In one embodiment, compounds of iron and the other desired ions are present in the solution in the stoichiometric ratio.

In one preferred embodiment, ions of nickel, zinc, and iron are present in a stoichiometric ratio of 0.5/0.5/2.0, respectively. In another preferred embodiment, ions of lithium and iron are present in the ratio of 0.5/2.5. In yet another preferred embodiment, ions of magnesium and iron are present in the ratio of 1.0/2.0. In another embodiment, ions of manganese and iron are present in the ratio 1.0/2.0. In yet another embodiment, ions of yttrium and iron are present in the ratio of 3.0/5.0. In yet another embodiment, ions of lanthanum, yttrium, and iron are present in the ratio of 0.5/2.5/5.0. In yet another embodiment, ions of neodymium, yttrium, gadolinium, and iron are present in the ratio of 1.0/1.07/0.93/5.0, or 1.0/1.1/0.9/5.0, or 1/1.12/0.88/5.0. In yet another embodiment, ions of samarium and iron are present in the ratio of 3.0/5.0. In yet another embodiment, ions of neodymium, samarium, and iron are present in the ratio of 0.1/2.9/5.0, or 0.25/2.75/5.0, or 0.375/2.625/5.0. In yet another embodiment, ions of neodymium, erbium, and iron are present in the ratio of 1.5/1.5/5.0. In yet another embodiment, samarium, yttrium, and iron ions are present in the ratio of 0.51/2.49/5.0, or 0.84/2.16/5.0, or 1.5/1.5/5.0. In yet another embodiment, ions of yttrium, gadolinium, and

iron are present in the ratio of 2.25/0.75/5.0, or 1.5/1.5/5.0, or 0.75/2.25/5.0. In yet another embodiment, ions of terbium, yttrium, and iron are present in the ratio of 0.8/2.2/5.0, or 1.0/2.0/5.0. In yet another embodiment, ions of dysprosium, aluminum, and iron are present in the ratio of 3/x/5-x, when x is from 0 to 1.0. In yet another embodiment, ions of dysprosium, gallium, and iron are also present in the ratio of 3/x/5-x. In yet another embodiment, ions of dysprosium, chromium, and iron are also present in the ratio of 3/x/5-x.

The ions present in the solution may be holmium, yttrium, and iron, present in the ratio of z/3-z/5.0, where z is from about 0 to 1.5.

The ions present in the solution may be erbium, gadolinium, and iron in the ratio of 1.5/1.5/5.0. The ions may be erbium, yttrium, and iron in the ratio of 1.5/1.5/1.5, or 0.5/2.5/5.0.

The ions present in the solution may be thulium, yttrium, and iron, in the ratio of 0.06/2.94/5.0.

The ions present in the solution may be ytterbium, yttrium, and iron, in the ratio of 0.06/2.94/5.0.

The ions present in the solution may be lutetium, yttrium, and iron in the ratio of y/3-y/5.0, wherein y is from 0 to 3.0.

The ions present in the solution may be iron, which can be used to form  $\text{Fe}_6\text{O}_8$  (two formula units of  $\text{Fe}_3\text{O}_4$ ). The ions present may be barium and iron in the ratio of 1.0/6.0, or 2.0/8.0. The ions present may be strontium and iron, in the ratio of 1.0/12.0. The ions present may be strontium, chromium, and iron in the ratio of 1.0/1.0/10.0, or 1.0/6.0/6.0. The ions present may be suitable for producing a ferrite of the formula

$(Me_x)_3^+ Ba_{1-x} Fe_{12} O_{19}$ , wherein Me is a rare earth selected from the group consisting of lanthanum, promethium, neodymium, samarium, europium, and mixtures thereof.

The ions present in the solution may contain barium, either lanthanum or promethium, iron, and cobalt in the ratio of  $1-a/a/12-a/a$ , wherein a is from 0.0 to 0.8.

The ions present in the solution may contain barium, cobalt, titanium, and iron in the ratio of  $1.0/b/b/12-2b$ , wherein b is from 0.0 to 1.6.

The ions present in the solution may contain barium, nickel or cobalt or zinc, titanium, and iron in the ratio of  $1.0/c/c/12-2c$ , wherein c is from 0.0 to 1.5.

The ions present in the solution may contain barium, iron, iridium, and zinc in the ratio of  $1.0/12-2d/d/d$ , wherein d is from 0.0 to 0.6.

The ions present in the solution may contain barium, nickel, gallium, and iron in the ratio of  $1.0/2.0/7.0/9.0$ , or  $1.0/2.0/5.0/11.0$ . Alternatively, the ions may contain barium, zinc, gallium or aluminum, and iron in the ratio of  $1.0/2.0/3.0/13.0$ .

Each of these ferrites is well known to those in the ferrite art and is described, e.g., in the aforementioned Von Aulock book.

The ions described above are preferably available in solution 10 in water-soluble form, such as, e.g., in the form of water-soluble salts. Thus, e.g., one may use the nitrates or the chlorides or the sulfates or the phosphates of the cations. Other anions which form soluble salts with the cation(s) also may be used.

Alternatively, one may use salts soluble in solvents other than water. Some of these other solvents which may be used to prepare the material include nitric acid, hydrochloric acid, phosphoric acid, sulfuric acid, and the like. As is well known to those skilled in the art, many other suitable solvents may be used; see, e.g., J. A. Riddick et al.,

"Organic Solvents, Techniques of Chemistry," Volume II, 3rd edition (Wiley-Interscience, New York, N.Y., 1970).

In one preferred embodiment, where a solvent other than water is used, each of the cations is present in the form of one or more of its oxides. For example, one may dissolve iron oxide in nitric acid, thereby forming a nitrate. For example, one may dissolve zinc oxide in sulfuric acid, thereby forming a sulfate. One may dissolve nickel oxide in hydrochloric acid, thereby forming a chloride. Other means of providing the desired cation(s) will be readily apparent to those skilled in the art.

In general, as long as the desired cation(s) are present in the solution, it is not significant how the solution was prepared.

In general, one may use commercially available reagent grade materials. Thus, by way of illustration and not limitation, one may use the following reagents available in the 1988-1989 Aldrich catalog (Aldrich Chemical Company, Inc., Milwaukee, Wis.): barium chloride, catalog number 31,866- 3; barium nitrate, catalog number 32,806-5; barium sulfate, catalog number 20,276-2; strontium chloride hexhydrate, catalog number 20,466-3; strontium nitrate, catalog number 20,449-8; yttrium chloride, catalog number 29,826-3; yttrium nitrate tetrahydrate, catalog number 21,723-9; yttrium sulfate octahydrate, catalog number 20,493-5. This list is merely illustrative, and other compounds which can be used will be readily apparent to those skilled in the art. Thus, any of the desired reagents also may be obtained from the 1989-1990 AESAR catalog (Johnson Matthey/AESAR Group, Seabrook, N.H.), the 1990/1991 Alfa catalog (Johnson Matthey/Alfa Products, Ward Hill, Ma.), the Fisher 88 catalog (Fisher Scientific, Pittsburgh, Pa.), and the like.

As long as the metals present in the desired ferrite material are present in solution 10 in the desired stoichiometry, it does not matter whether they are present in the form of a salt, an oxide, or in another form. In one embodiment, however, it is preferred to have the solution contain either the salts of such metals, or their oxides.

The solution 10 of the compounds of such metals preferably will be at a concentration of from about 0.01 to about 1,000 grams of said reagent compounds per liter of the resultant solution. As used in this specification, the term liter refers to 1,000 cubic centimeters.

In one embodiment, it is preferred that solution 10 have a concentration of from about 1 to about 300 grams per liter and, preferably, from about 25 to about 170 grams per liter. It is even more preferred that the concentration of said solution 10 be from about 100 to about 160 grams per liter. In an even more preferred embodiment, the concentration of said solution 10 is from about 140 to about 160 grams per liter.

In one preferred embodiment, aqueous solutions of nickel nitrate, and iron nitrate with purities of at least 99.9 percent are mixed in the molar ratio of 1:2 and then dissolved in distilled water to form a solution with a concentration of 150 grams per liter.

In one preferred embodiment, aqueous solutions of nickel nitrate, zinc nitrate, and iron nitrate with purities of at least 99.9 percent are mixed in the molar ratio of 0.5:0.5:2 and then dissolved in distilled water to form a solution with a concentration of 150 grams per liter.

In one preferred embodiment, aqueous solutions of zinc nitrate, and iron nitrate with purities of at least 99.9 percent are mixed in the molar ratio of 1:2 and then dissolved in distilled water to form a solution with a concentration of 150 grams per liter.

In one preferred embodiment, aqueous solutions of nickel chloride, and iron chloride with purities of at least 99.9 percent are mixed in the molar ratio of 1:2 and then dissolved in distilled water to form a solution with a concentration of 150 grams per liter.

In one preferred embodiment, aqueous solutions of nickel chloride, zinc chloride, and iron chloride with purities of at least 99.9 percent are mixed in the molar ratio of 0.5:0.5:2 and then dissolved in distilled water to form a solution with a concentration of 150 grams per liter.

In one preferred embodiment, aqueous solutions of zinc chloride, and iron chloride with purities of at least 99.9 percent are mixed in the molar ratio of 1:2 and then dissolved in distilled water to form a solution with a concentration of 150 grams per liter.

In one embodiment, mixtures of chlorides and nitrides may be used. Thus, for example, in one preferred embodiment, the solution is comprised of both iron chloride and nickel nitrate in the molar ratio of 2.0/1.0.

Referring again to Figure 1, and to the preferred embodiment depicted therein, the solution 10 in misting chamber 12 is preferably caused to form into an aerosol, such as a mist.

The term aerosol, as used in this specification, refers to a suspension of ultramicroscopic solid or liquid particles in air or gas, such as smoke, fog, or mist. See, e.g., page 15 of "A dictionary of mining, mineral, and related terms," edited by Paul W. Thrush (U.S. Department of the Interior, Bureau of Mines, 1968), the disclosure of which is hereby incorporated by reference into this specification.

As used in this specification, the term mist refers to gas-suspended liquid particles which have diameters less than 10 microns.

The aerosol/mist consisting of gas-suspended liquid particles with diameters less than 10 microns may be produced from solution 10 by any conventional means that causes sufficient mechanical disturbance of said solution. Thus, one may use mechanical vibration. In one preferred embodiment, ultrasonic means are used to mist solution 10. As is known to those skilled in the art, by varying the means used to cause such mechanical disturbance, one can also vary the size of the mist particles produced.

As is known to those skilled in the art, ultrasonic sound waves (those having frequencies above 20,000 hertz) may be used to mechanically disturb solutions and cause them to mist. Thus, by way of illustration, one may use the ultrasonic nebulizer sold by the DeVilbiss Health Care, Inc. of Somerset, Pennsylvania; see, e.g., the "Instruction Manual" for the "Ultra-Neb 99 Ultrasonic Nebulizer, publication A-850-C (published by DeVilbiss, Somerset, Pa., 1989).

In the embodiment shown in Figure 1, the oscillators of ultrasonic nebulizer 14 are shown contacting an exterior surface of misting chamber 12. In this embodiment, the ultrasonic waves produced by the oscillators are transmitted via the walls of the misting chamber 12 and effect the misting of solution 10.

In another embodiment, not shown, the oscillators of ultrasonic nebulizer 14 are in direct contact with solution 10.

In one embodiment, it is preferred that the ultrasonic power used with such machine should be in excess of one watt and, more preferably, in excess of 10 watts. In one embodiment, the power used with such machine exceeds about 50 watts.

During the time solution 10 is being caused to mist, it is preferably contacted with carrier gas to apply pressure to the solution and mist. It is preferred that a sufficient

amount of carrier gas be introduced into the system at a sufficiently high flow rate so that pressure on the system is in excess of atmospheric pressure. Thus, for example, in one embodiment wherein chamber 12 has a volume of about 200 cubic centimeters, the flow rate of the carrier gas was from about 100 to about 150 milliliters per minute.

In one embodiment, the carrier gas 16 is introduced via feeding line 18 at a rate sufficient to cause solution 10 to mist at a rate of from about 0.5 to about 20 milliliters per minute. In one embodiment, the misting rate of solution 10 is from about 1.0 to about 3.0 milliliters per minute.

Substantially any gas that facilitates the formation of plasma may be used as carrier gas 16. Thus, by way of illustration, one may use oxygen, air, argon, nitrogen, and the like. It is preferred that the carrier gas used be a compressed gas under a pressure in excess 760 millimeters of mercury. In this embodiment, the use of the compressed gas facilitates the movement of the mist from the misting chamber 12 to the plasma region 22.

The misting container 12 may be any reaction chamber conventionally used by those skilled in the art and preferably is constructed out of such acid-resistant materials such as glass, plastic, and the like.

The mist from misting chamber 12 is fed via misting outlet line 20 into the plasma region 22 of plasma reactor 24. In plasma reactor 24, the mist is mixed with plasma generated by plasma gas 26 and subjected to radio frequency radiation provided by a radio-frequency coil 28.

The plasma reactor 24 provides energy to form plasma and to cause the plasma to react with the mist. Any of the plasmas reactors well known to those skilled in the art

may be used as plasma reactor 24. Some of these plasma reactors are described in J. Mort et al.'s "Plasma Deposited Thin Films" (CRC Press Inc., Boca Raton, Fla., 1986); in "Methods of Experimental Physics," Volume 9--Parts A and B, Plasma Physics (Academic Press, New York, 1970/1971); and in N. H. Burlingame's "Glow Discharge Nitriding of Oxides," Ph.D. thesis (Alfred University, Alfred, N.Y., 1985), available from University Microfilm International, Ann Arbor, Mich.

In one preferred embodiment, the plasma reactor 24 is a "model 56 torch" available from the TAFA Inc. of Concord, N.H. It is preferably operated at a frequency of about 4 megahertz and an input power of 30 kilowatts.

Referring again to Figure 1, and to the preferred embodiment depicted therein, it will be seen that into feeding lines 30 and 32 is fed plasma gas 26. As is known to those skilled in the art, a plasma can be produced by passing gas into a plasma reactor. A discussion of the formation of plasma is contained in B. Chapman's "Glow Discharge Processes" (John Wiley & Sons, New York, 1980)

In one preferred embodiment, the plasma gas used is a mixture of argon and oxygen. In another embodiment, the plasma gas is a mixture of nitrogen and oxygen. In yet another embodiment, the plasma gas is pure argon or pure nitrogen.

When the plasma gas is pure argon or pure nitrogen, it is preferred to introduce into the plasma reactor at a flow rate of from about 5 to about 30 liters per minute.

When a mixture of oxygen and either argon or nitrogen is used, the concentration of oxygen in the mixture preferably is from about 1 to about 40 volume percent and, more preferably, from about 15 to about 25 volume percent. When such a mixture is used, the flow rates of each gas in the mixture should be adjusted to obtain the desired

gas concentrations. Thus, by way of illustration, in one embodiment which uses a mixture of argon and oxygen, the argon flow rate is 15 liters per minute, and the oxygen flow rate is 40 liters per minute.

In one embodiment, auxiliary oxygen 34 is fed into the top of reactor 24, between the plasma region 22 and the flame region 40, via lines 36 and 38. In this embodiment, the auxiliary oxygen is not involved in the formation of plasma but is involved in the enhancement of the oxidation of the ferrite material.

Radio frequency energy is applied to the reagents in the plasma reactor 24, and it causes vaporization of the mist.

In general, the energy is applied at a frequency of from about 100 to about 30,000 kilohertz. In one embodiment, the radio frequency used is from about 1 to 20 megahertz. In another embodiment, the radio frequency used is from about 3 to about 5 megahertz.

As is known to those skilled in the art, such radio frequency alternating currents may be produced by conventional radio frequency generators. Thus, by way of illustration, said TAPA Inc. "model 56 torch" may be attached to a radio frequency generator rated for operation at 35 kilowatts which manufactured by Lepel Company (a division of TAFA Inc.) and which generates an alternating current with a frequency of 4 megaherz at a power input of 30 kilowatts. Thus, e.g., one may use an induction coil driven at 2.5-5.0 megahertz which is sold as the "PLASMOC 2" by ENI Power Systems, Inc. of Rochester, New York.

The use of these type of radio-frequency generators is described in the Ph.D. theses entitled (1) "Heat Transfer Mechanisms in High-Temperature Plasma Processing

of Glasses," Donald M. McPherson (Alfred University, Alfred, N.Y., January, 1988) and (2) the aforementioned Nicholas H. Burlingame's "Glow Discharge Nitriding of Oxides."

The plasma vapor 23 formed in plasma reactor 24 is allowed to exit via the aperture 42 and can be visualized in the flame region 40. In this region, the plasma contacts air which is at a lower temperature than the plasma region 22, and a flame is visible. A theoretical model of the plasma/flame is presented on pages 88 et seq. of said McPherson thesis.

The vapor 44 present in flame region 40 is propelled upward towards substrate 46. Any material onto which vapor 44 will condense may be used as a substrate. Thus, by way of illustration, one may use nonmagnetic materials such alumina, glass, gold-plated ceramic materials, and the like. In one embodiment, substrate 46 consists essentially of a magnesium oxide material such as single crystal magnesium oxide, polycrystalline magnesium oxide, and the like.

In another embodiment, the substrate 46 consists essentially of zirconia such as, e.g., yttrium stabilized cubic zirconia.

In another embodiment, the substrate 46 consists essentially of a material selected from the group consisting of strontium titanate, stainless steel, alumina, sapphire, and the like.

The aforementioned listing of substrates is merely meant to be illustrative, and it will be apparent that many other substrates may be used. Thus, by way of illustration, one may use any of the substrates mentioned in M. Sayer's "Ceramic Thin Films . . ." article, supra. Thus, for example, in one embodiment it is preferred to use one or more of the

substrates described on page 286 of "Superconducting Devices," edited by S. T. Ruggiero et al. (Academic Press, Inc., Boston, 1990).

One advantage of applicants' process is that the substrate may be of substantially any size or shape, and it may be stationary or movable. Because of the speed of the coating process, the substrate 46 may be moved across the aperture 42 and have any or all of its surface be coated with the 48.

As will be apparent to those skilled in the art, in the embodiment depicted in Figure 1, the substrate 46 and the coating 48 are not drawn to scale but have been enlarged to the sake of ease of representation.

Referring again to Figure 1, the substrate 46 may be at ambient temperature. Alternatively, one may use additional heating means to heat the substrate prior to, during, or after deposition of the coating.

In one preferred embodiment, a heater (not shown) is used to heat the substrate to a temperature of from about 100 to about 800 degrees centigrade.

In one aspect of this embodiment, temperature sensing means (not shown) may be used to sense the temperature of the substrate and, by feedback means (not shown) adjust the output of the heater (not shown). In one embodiment, not shown, when the substrate 46 is relatively near flame region 40, optical pyrometry measurement means (not shown) may be used to measure the temperature near the substrate.

In one embodiment, a shutter (not shown) is used to selectively interrupt the flow of vapor 44 to substrate 46. This shutter, when used, should be used prior to the time the flame region has become stable; and the vapor should preferably not be allowed to impinge upon the substrate prior to such time.

The substrate 46 may be moved in a plane which is substantially parallel to the top of plasma chamber 24. Alternatively, or additionally, it may be moved in a plane which is substantially perpendicular to the top of plasma chamber 24. In one embodiment, the substrate 46 is moved stepwise along a predetermined path to coat the substrate only at certain predetermined areas.

In one embodiment, rotary substrate motion is utilized to expose as much of the surface of a complex-shaped article to the coating. This rotary substrate motion may be effected by conventional means. See, e.g., "Physical Vapor Deposition," edited by Russell J. Hill (Temescal Division of The BOC Group, Inc., Berkeley, Calif., 1986).

The process of this embodiment of the invention allows one to coat an article at a deposition rate of from about 0.01 to about 10 microns per minute and, preferably, from about 0.1 to about 1.0 microns per minute, with a substrate with an exposed surface of 35 square centimeters. One may determine the thickness of the film coated upon said reference substrate material (with an exposed surface of 35 square centimeters) by means well known to those skilled in the art.

The film thickness can be monitored in situ, while the vapor is being deposited onto the substrate. Thus, by way of illustration, one may use an IC-6000 thin film thickness monitor (as referred to as "deposition controller") manufactured by Leybold Inficon Inc. of East Syracuse, N.Y.

The deposit formed on the substrate may be measured after the deposition by standard profilometry techniques. Thus, e.g., one may use a DEKTAk Surface Profiler, model number 900051 (available from Sloan Technology Corporation, Santa Barbara, California).

In general, at least about 80 volume percent of the particles in the as-deposited film are smaller than about 1 microns. It is preferred that at least about 90 percent of such particles are smaller than 1 micron. Because of this fine grain size, the surface of the film is relatively smooth.

In one preferred embodiment, the as-deposited film is post-annealed.

It is preferred that the generation of the vapor in plasma reactor 24 be conducted under substantially atmospheric pressure conditions. As used in this specification, the term "substantially atmospheric" refers to a pressure of at least about 600 millimeters of mercury and, preferably, from about 600 to about 1,000 millimeters of mercury. It is preferred that the vapor generation occur at about atmospheric pressure. As is well known to those skilled in the art, atmospheric pressure at sea level is 760 millimeters of mercury.

The process of this invention may be used to produce coatings on a flexible substrate such as, e.g., stainless steel strips, silver strips, gold strips, copper strips, aluminum strips, and the like. One may deposit the coating directly onto such a strip. Alternatively, one may first deposit one or more buffer layers onto the strip(s). In other embodiments, the process of this invention may be used to produce coatings on a rigid or flexible cylindrical substrate, such as a tube, a rod, or a sleeve.

Referring again to Figure 1, and in the embodiment depicted therein, as the coating 48 is being deposited onto the substrate 46, and as it is undergoing solidification thereon, it is preferably subjected to a magnetic field produced by magnetic field generator 50.

It is preferred that the magnetic field produced by the magnetic field generator 50 have a field strength of from about 2 Gauss to about 40 Tesla.

It is preferred to expose the deposited material for at least 10 seconds and, more preferably, for at least 30 seconds, to the magnetic field, until the magnetic moments of the nano-sized particles being deposited have been substantially aligned.

As used herein, the term "substantially aligned" means that the inductance of the device being formed by the deposited nano-sized particles is at least 90 percent of its maximum inductance. One may determine when such particles have been aligned by measuring the inductance, the permeability, and/or the hysteresis loop of the deposited material.

One may measure the degree of alignment of the deposited particles with an impedance meter, a inductance meter, or a SQUID.

In one embodiment, the degree of alignment of the deposited particles is measured with an inductance meter. One may use, e.g., a conventional conductance meter such as, e.g., the conductance meters disclosed in United States patents 4,779,462, 4,937,995, 5,728,814 (apparatus for determining and recording injection doses in syringes using electrical inductance), 6,318,176, 5,014,012, 4,869,598, 4,258,315 (inductance meter), 4,045,728 (direct reading inductance meter), 6,252,923, 6,194,898, 6,006,023 (molecular sensing apparatus), 6,048,692 (sensors for electrically sensing binding events for supported molecular receptors), and the like. The entire disclosure of each of these United States patents is hereby incorporated by reference into this specification.

When measuring the inductance of the coated sample, the inductance is preferably measured using an applied wave with a specified frequency. As the magnetic moments of the coated samples align, the inductance increases until a specified value; and it rises in accordance with a specified time constant in the measurement circuitry.

In one embodiment, the deposited material is contacted with the magnetic field until the inductance of the deposited material is at least about 90 percent of its maximum value under the measurement circuitry. At this time, the magnetic particles in the deposited material has been aligned to at least about 90 percent of the maximum extent possible for maximizing the inductance of the sample.

By way of illustration and not limitation, a metal rod with a diameter of 1 micron and a length of 1 millimeter, when uncoated with magnetic nano-sized particles, might have an inductance of about 1 nanohenry. When this metal rod is coated with, e.g., nano-sized ferrites, then the inductance of the coated rod might be 5 nanohenries or more. When the magnetic moments of the coating are aligned, then the inductance might increase to 50 nanohenries, or more. As will be apparent to those skilled in the art, the inductance of the coated article will vary, e.g., with the shape of the article and also with the frequency of the applied electromagnetic field.

One may use any of the conventional magnetic field generators known to those skilled in the art to produce such as magnetic field. Thus, e.g., one may use one or more of the magnetic field generators disclosed in United States patents 6,503,364, 6,377,149 (magnetic field generator for magnetron plasma generation), 6,353,375 (magnetostatic wave device), 6,340,888 (magnetic field generator for MRI), 6,336,989, 6,335,617 (device for calibrating a magnetic field generator), 6,313,632, 6,297,634, 6,275,128, 6,246,066 (magnetic field generator and charged particle beam irradiator), 6,114,929 (magnetostatic wave device), 6,099,459 (magnetic field generating device and method of generating and applying a magnetic field), 5,795,212, 6,106,380 (deterministic magnetorheological finishing), 5,839,944 (apparatus for deterministic

magnetorheological finishing), 5,971,835 (system for abrasive jet shaping and polishing of a surface using a magnetorheological fluid), 5,951,369, 6,506,102 (system for magnetorheological finishing of substrates), 6,267,651, 6,309,285 (magnetic wiper), and the like. The entire disclosure of each of these United States patents is hereby incorporated by reference into this specification.

In one embodiment, the magnetic field is 1.8 Tesla or less. In this embodiment, the magnetic field can be applied with, e.g., electromagnets disposed around a coated substrate.

For fields greater than about 2 Tesla, one may use superconducting magnets that produce fields as high as 40 Tesla. Reference may be had, e.g., to United States patents 5,319,333 (superconducting homogeneous high field magnetic coil), 4,689,563, 6,496,091 (superconducting magnet arrangement), 6,140,900 (asymmetric superconducting magnets for magnetic resonance imaging), 6,476,700 (superconducting magnet system), 4,763,404 (low current superconducting magnet), 6,172,587 (superconducting high field magnet), 5,406,204, and the like. The entire disclosure of each of these United States patents is hereby incorporated by reference into this specification.

In one embodiment, no magnetic field is applied to the deposited coating while it is being solidified. In this embodiment, as will be apparent to those skilled in the art, there still may be some alignment of the magnetic domains in a plane parallel to the surface of substrate as the deposited particles are locked into place in a matrix (binder) deposited onto the surface.

In one embodiment, depicted in Figure 1, the magnetic field 52 is preferably delivered to the coating 48 in a direction that is substantially parallel to the surface 56 of the substrate 46. In another embodiment, depicted in Figure 1, the magnetic field 58 is delivered in a direction that is substantially perpendicular to the surface 56. In yet another embodiment, the magnetic field 60 is delivered in a direction that is angularly disposed vis-à-vis surface 56 and may form, e.g., an obtuse angle (as in the case of field 62). As will be apparent, combinations of these magnetic fields may be used.

Figure 2 is a flow diagram of another process which may be used to make the nanomagnetic compositions of this invention. Referring to Figure 2, and to the preferred process depicted therein, it will be seen that nano-sized ferromagnetic material(s), with a particle size less than about 100 nanometers, is preferably charged via line 60 to mixer 62. It is preferred to charge a sufficient amount of such nano-sized material(s) so that at least about 10 weight percent of the mixture formed in mixer 62 is comprised of such nano-sized material. In one embodiment, at least about 40 weight percent of such mixture in mixer 62 is comprised of such nano-sized material. In another embodiment, at least about 50 weight percent of such mixture in mixer 62 is comprised of such nano-sized material.

In one embodiment, one or more binder materials are charged via line 64 to mixer 62. In one embodiment, the binder used is a ceramic binder. These ceramic binders are well known. Reference may be had, e.g., to pages 172-197 of James S. Reed's "Principles of Ceramic Processing," Second Edition (John Wiley & Sons, Inc., New York, New York, 1995). As is disclosed in the Reed book, the binder may be a clay binder (such as fine kaolin, ball clay, and bentonite), an organic colloidal particle binder

(such as microcrystalline cellulose), a molecular organic binder (such as natural gums, polysaccharides, lignin extracts, refined alginate, cellulose ethers, polyvinyl alcohol, polyvinylbutyral, polymethyl methacrylate, polyethylene glycol, paraffin, and the like.). etc.

In one embodiment, the binder is a synthetic polymeric or inorganic composition. Thus, and referring to George S. Brady et al.'s "Materials Handbook," (McGraw-Hill, Inc., New York, New York 1991), the binder may be acrylonitrile-butadiene-styrene (see pages 5-6), an acetal resin (see pages 6-7), an acrylic resin (see pages 10-12), an adhesive composition (see pages 14-18), an alkyd resin (see page 27-28), an allyl plastic (see pages 31-32), an amorphous metal (see pages 53-54), a biocompatible material (see pages 95-98), boron carbide (see page 106), boron nitride (see page 107), camphor (see page 135), one or more carbohydrates (see pages 138-140), carbon steel (see pages 146-151), casein plastic (see page 157), cast iron (see pages 159-164), cast steel (see pages 166-168), cellulose (see pages 172-175), cellulose acetate (see pages 175-177), cellulose nitrate (see pages 177), cement (see page 178-180), ceramics (see pages 180-182), cermets (see pages 182-184), chlorinated polyethers (see pages 191-191), chlorinated rubber (see pages 191-193), cold-molded plastics (see pages 220-221), concrete (see pages 225-227), conductive polymers and elastomers (see pages 227-228), degradable plastics (see pages 261-262), dispersion-strengthened metals (see pages 273-274), elastomers (see pages 284-290), enamel (see pages 299-301), epoxy resins (see pages 301-302), expansive metal (see page 313), ferrosilicon (see page 327), fiber-reinforced plastics (see pages 334-335), fluoroplastics (see pages 345-347), foam materials (see pages 349-351), fusible alloys (see pages 362-364), glass (see pages 376-383), glass-ceramic materials (see pages

383-384), gypsum (see pages 406-407), impregnated wood (see pages 422-423), latex (see pages 456-457), liquid crystals (see page 479). lubricating grease (see pages 488-492), magnetic materials (see pages 505-509), melamine resin (see pages 5210-521), metallic materials (see pages 522-524), nylon (see pages 567-569), olefin copolymers (see pages 574-576), phenol-formaldehyde resin (see pages 615-617), plastics (see pages 637-639), polyarylates (see pages 647-648), polycarbonate resins (see pages 648), polyester thermoplastic resins (see pages 648-650), polyester thermosetting resins (see pages 650-651), polyethylenes (see pages 651-654), polyphenylene oxide (see pages 644-655), polypropylene plastics (see pages 655-656), polystyrenes (see pages 656-658), proteins (see pages 666-670), refractories (see pages 691-697), resins (see pages 697-698), rubber (see pages 706-708), silicones (see pages 747-749), starch (see pages 797-802), superalloys (see pages 819-822), superpolymers (see pages 823-825), thermoplastic elastomers (see pages 837-839), urethanes (see pages 874-875), vinyl resins (see pages 885-888), wood (see pages 912-916), mixtures thereof, and the like.

Referring again to Figure 2, one may charge to line 64 either one or more of these "binder material(s)" and/or the precursor(s) of these materials that, when subjected to the appropriate conditions in former 66, will form the desired mixture of nanomagnetic material and binder.

Referring again to Figure 2, and in the preferred process depicted therein, the mixture within mixer 62 is preferably stirred until a substantially homogeneous mixture is formed. Thereafter, it may be discharged via line 65 to former 66.

One process for making a fluid composition comprising nanomagnetic particles is disclosed in United States patent 5,804,095, "Magnetorheological Fluid Composition,"

of Jacobs et al; the disclosure of this patent is incorporated herein by reference. In this patent, there is disclosed a process comprising numerous material handling steps used to prepare a nanomagnetic fluid comprising iron carbonyl particles. One suitable source of iron carbonyl particles having a median particle size of 3.1 microns is the GAF Corporation.

The process of Jacobs et al, is applicable to the present invention, wherein such nanomagnetic fluid further comprises a polymer binder, thereby forming a nanomagnetic paint. In one embodiment, the nanomagnetic paint is formulated without abrasive particles of cerium dioxide. In another embodiment, the nanomagnetic fluid further comprises a polymer binder, and aluminum nitride is substituted for cerium dioxide.

There are many suitable mixing processes and apparatus for the milling, particle size reduction, and mixing of fluids comprising solid particles. For example, e.g., iron carbonyl particles or other ferromagnetic particles of the paint may be further reduced to a size on the order of 100 nanometers or less, and/or thoroughly mixed with a binder polymer and/or a liquid solvent by the use of a ball mill, a sand mill, a paint shaker holding a vessel containing the paint components and hard steel or ceramic beads; a homogenizer (such as the Model Ytron Z made by the Ytron Quadro Corporation of Chesham, United Kingdom, or the Microfluidics M700 made by the MFIC Corporation of Newton, Ma.), a powder dispersing mixer (such as the Ytron Cyclon mixer, or the Ytron Cyclon mixer, or the Ytron PID mixer by the Ytron Quadro Corporation); a grinding mill (such as the Model F10 Mill by the Ytron Quadro Corporation); high shear mixers (such as the Ytron Y mixer by the Ytron Quadro Corporation), the Silverson Laboratory Mixer sold by the Silverson Corporation of East Longmeadow, Ma., and the

like. The use of one or more of these apparatus in series or in parallel may produce a suitably formulated nanomagnetic paint.

Referring again to Figure 2, the former 66 is preferably equipped with an input line 68 and an exhaust line 70 so that the atmosphere within the former can be controlled. One may utilize an ambient atmosphere, an inert atmosphere, pure nitrogen, pure oxygen, mixtures of various gases, and the like. Alternatively, or additionally, one may use lines 68 and 70 to afford subatmospheric pressure, atmospheric pressure, or superatmospheric pressure within former 66.

In the embodiment depicted, former 66 is also preferably comprised of an electromagnetic coil 72 that, in response from signals from controller 74, can control the extent to which, if any, a magnetic field is applied to the mixture within the former 66 (and also within the mold 67 and/or the spinnerette 69).

The controller 74 is also adapted to control the temperature within the former 66 by means of heating/cooling assembly.

In the embodiment depicted in Figure 2, a sensor 78 preferably determines the extent to which the desired nanomagnetic properties have been formed with the nano-sized material in the former 66; and, as appropriate, the sensor 78 imposes a magnetic field upon the mixture within the former 66 until the desired properties have been obtained.

In one embodiment, the sensor 78 is the inductance meter discussed elsewhere in this specification; and the magnetic field is applied until at least about 90 percent of the maximum inductance obtainable with the alignment of the magnetic moments has been obtained.

The magnetic field is preferably imposed until the nano-sized particles within former 78 (and the material with which it is admixed) have a mass density of at least about 0.001 grams per cubic centimeter (and preferably at least about 0.01 grams per cubic centimeter), a saturation magnetization of from about 1 to about 36,000 Gauss, a coercive force of from about 0.01 to about 5,000 Oersteds, and a relative magnetic permeability of from about 1 to about 500,000.

When the mixture within former 66 has the desired combination of properties (as reflected, e.g., by its substantially maximum inductance) and/or prior to that time, some or all of such mixture may be discharged via line 80 to a mold/extruder 67 wherein the mixture can be molded or extruded into a desired shape. A magnetic coil 72 also preferably may be used in mold/extruder 67 to help align the nano-sized particles.

Alternatively, or additionally, some or all of the mixture within former 66 may be discharged via line 82 to a spinnerette 69, wherein it may be formed into a fiber (not shown).

As will be apparent, one may make fibers by the process indicated that have properties analogous to the nanomagnetic properties of the coating 135 (see Figure 6A), and/or nanoelectrical properties of the coating 141 (see Figure 6B), and/or nanothermal properties of the coating 145 (see Figure 6E). Such fiber or fibers may be made into fabric by conventional means. By the appropriate selection and placement of such fibers, one may produce a shielded fabric which provides protection against high magnetic voltages and/or high voltages and/or excessive heat.

Thus, in one embodiment, nanomagnetic and/or nanoelectrical and/or nanothermal fibers are woven together to produce a garment that will shield from the

adverse effects of radiation such as, e.g., radiation experienced by astronauts in outer space.

Alternatively, or additionally, some or all of the mixture within former 66 may be discharged via line 84 to a direct writing applicator 90, such as a MicroPen applicator manufactured by OhmCraft Incorporated of Honeoye Falls, NY. Such an applicator is disclosed in United States patent 4,485,387, the disclosure of which is incorporated herein by reference. The use of this applicator to write circuits and other electrical structures is described in, e.g., United States patent 5,861,558 of Buhl et al, "Strain Gauge and Method of Manufacture", the disclosure of which is incorporated herein by reference.

In one preferred embodiment, the nanomagnetic, nanoelectrical, and/or nanothermal compositions of the present invention, along with various conductor, resistor, capacitor, and inductor formulations are dispensed by the MicroPen device, to fabricate the circuits and structures of the present invention on devices such as, e.g. catheters and other biomedical devices.

In one preferred embodiment, involving the writing of nanomagnetic circuit patterns and/or thin films, the direct writing applicator 90 (as disclosed in U.S. patent 4,485,387) comprises an applicator tip 92 and an annular magnet 94, which provides a magnetic field 72. The use of such an applicator 90 to apply nanomagnetic coatings is particularly beneficial, because the presence of the magnetic field from magnet 94, through which the nanomagnetic fluid flows serves to orient the magnetic particles *in situ* as such nanomagnetic fluid is applied to a substrate. Such an orienting effect is described in United States patent 5,971,835, the disclosure of which is incorporated herein by

reference. Once the nanomagnetic particles are properly oriented by such a field, or by another magnetic field source, the applied coating is cured by heating, by ultraviolet radiation, by an electron beam, or by other suitable means.

In one embodiment, not shown, one may form compositions comprised of nanomagnetic particles and/or nanoelectrical particles and/or nanothermal particles and/or other nano-sized particles by a sol-gel process. Thus, by way of illustration and not limitation, one may use one or more of the processes described in United States patents 6,287,639 (nanocomposite material comprised of inorganic particles and silanes), 6,337,117 (optical memory device comprised of nano-sized luminous material), 6,527,972 ((magnetorheological polymer gels), 6,589,457 (process for the deposition of ruthenium oxide thin films), 6,657,001 (polysiloxane compositions comprised of inorganic particles smaller than 100 nanometers), 6,666,935 (sol-gel manufactured energetic materials), and the like. The entire disclosure of each of these United States patents is hereby incorporated by reference into this specification.

#### Nanomagnetic compositions comprised of moieties A, B, and C

The aforementioned process described in the preceding section of this specification, and the other processes described in this specification, may each be adapted to produce other, comparable nanomagnetic structures, as is illustrated in Figure 3.

Referring to Figure 3, and in the preferred embodiment depicted therein, a phase diagram 100 is presented. As is illustrated by this phase diagram 100, the nanomagnetic material used in this embodiment of the invention preferably is comprised of one or more of moieties A, B, and C. The moieties A, B, and C described in reference to phase 100 of

Figure 3 are not necessarily the same as the moieties A, B, and C described in reference to phase diagram 2000 of Figure 24.

The moiety A depicted in phase diagram 100 is preferably comprised of a magnetic element selected from the group consisting of a transition series metal, a rare earth series metal, or actinide metal, a mixture thereof, and/or an alloy thereof.

As is known to those skilled in the art, the transition series metals include chromium, manganese, iron, cobalt, and nickel. One may use alloys of iron, cobalt and nickel such as, e.g., iron--aluminum, iron--carbon, iron--chromium, iron--cobalt, iron--nickel, iron nitride ( $Fe^3N$ ), iron phosphide, iron-silicon, iron-vanadium, nickel-cobalt, nickel-copper, and the like. One may use alloys of manganese such as, e.g., manganese-aluminum, manganese-bismuth, MnAs, MnSb, MnTe, manganese-copper, manganese-gold, manganese-nickel, manganese-sulfur and related compounds, manganese-antimony, manganese-tin, manganese-zinc, Heusler alloy W, and the like. One may use compounds and alloys of the iron group, including oxides of the iron group, halides of the iron group, borides of the transition elements, sulfides of the iron group, platinum and palladium with the iron group, chromium compounds, and the like.

One may use a rare earth and/or actinide metal such as, e.g., Ce, Pr, Nd, Pm, Sm, Eu, Gd, Tb, Dy, Ho, Er, Tm, Yb, Lu, La, mixtures thereof, and alloys thereof. One may also use one or more of the actinides such as, e.g., the actinides of Th, Pa, U, Np, Pu, Am, Cm, Bk, Cf, Es, Fm, Md, No, Lr, Ac, and the like.

These moieties, compounds thereof, and alloys thereof are well known and are described, e.g., in the text of R.S. Tebble et al. entitled "Magnetic Materials."

In one preferred embodiment, illustrated in Figure 3, moiety A is selected from the group consisting of iron, nickel, cobalt, alloys thereof, and mixtures thereof. In this embodiment, the moiety A is magnetic, i.e., it has a relative magnetic permeability of from about 1 to about 500,000. As is known to those skilled in the art, relative magnetic permeability is a factor, being a characteristic of a material, which is proportional to the magnetic induction produced in a material divided by the magnetic field strength; it is a tensor when these quantities are not parallel. See, e.g., page 4-128 of E.U. Condon et al.'s "Handbook of Physics" (McGraw-Hill Book Company, Inc., New York, New York, 1958).

The moiety A of Figure 3 also preferably has a saturation magnetization of from about 1 to about 36,000 Gauss, and a coercive force of from about 0.01 to about 5,000 Oersteds.

The moiety A of Figure 3 may be present in the nanomagnetic material either in its elemental form, as an alloy, in a solid solution, or as a compound.

It is preferred at least about 1 mole percent of moiety A be present in the nanomagnetic material (by total moles of A, B, and C), and it is more preferred that at least 10 mole percent of such moiety A be present in the nanomagnetic material (by total moles of A, B, and C). In one embodiment, at least 60 mole percent of such moiety A is present in the nanomagnetic material, (by total moles of A, B, and C.)

In the embodiment depicted in Figure 3, in addition to moiety A, it is preferred to have moiety B be present in the nanomagnetic material. In this embodiment, moieties A and B are admixed with each other. The mixture may be a physical mixture, it may be a solid solution, it may be comprised of an alloy of the A/B moieties, etc.

In one embodiment, the magnetic material A is dispersed within nonmagnetic material B. This embodiment is depicted schematically in Figure 4.

Referring to Figure 4, and in the preferred embodiment depicted therein, it will be seen that A moieties 102, 104, and 106 are preferably separated from each other either at the atomic level and/or at the nanometer level. The A moieties may be, e.g., A atoms, clusters of A atoms, A compounds, A solid solutions, etc. Regardless of the form of the A moiety, it preferably has the magnetic properties described hereinabove.

In the embodiment depicted in Figure 4, each A moiety preferably produces an independent magnetic moment. The coherence length (L) between adjacent A moieties is, on average, preferably from about 0.1 to about 100 nanometers and, more preferably, from about 1 to about 50 nanometers.

Thus, referring again to Figure 4, the normalized magnetic interaction between adjacent A moieties 102 and 104, and also between 104 and 106, is preferably described by the formula  $M = \exp(-x/L)$ , wherein M is the normalized magnetic interaction, exp is the base of the natural logarithm (and is approximately equal to 2.71828), x is the distance between adjacent A moieties, and L is the coherence length. M, the normalized magnetic interaction, preferably ranges from about  $3 \times 10^{-44}$  to about 1.0. In one preferred embodiment, M is from about 0.01 to 0.99. In another preferred embodiment, M is from about 0.1 to about 0.9.

In one embodiment, and referring again to Figure 4, x is preferably measured from the center 101 of A moiety 102 to the center 103 of A moiety 104; and x is preferably equal to from about 0.00001 times L to about 100 times L.

In one embodiment, the ratio of x/L is at least 0.5 and, preferably, at least 1.5.

Referring again to Figure 3, and in the preferred embodiment depicted therein, the nanomagnetic material may be comprised of 100 percent of moiety A, provided that such moiety A has the required normalized magnetic interaction (M). Alternatively, the nanomagnetic material may be comprised of both moiety A and moiety B.

When moiety B is present in the nanomagnetic material, in whatever form or forms it is present, it is preferred that it be present at a mole ratio (by total moles of A and B) of from about 1 to about 99 percent and, preferably, from about 10 to about 90 percent.

The B moiety, in whatever form it is present, is preferably nonmagnetic, i.e., it has a relative magnetic permeability of 1.0; without wishing to be bound to any particular theory, applicants believe that the B moiety acts as buffer between adjacent A moieties. One may use, e.g., such elements as silicon, aluminum, boron, platinum, tantalum, palladium, yttrium, zirconium, titanium, calcium, beryllium, barium, silver, gold, indium, lead, tin, antimony, germanium, gallium, tungsten, bismuth, strontium, magnesium, zinc, and the like.

In one embodiment, and without wishing to be bound to any particular theory, it is believed that B moiety provides plasticity to the nanomagnetic material that it would not have but for the presence of such B moiety. In one aspect of this embodiment, it is preferred that the bending radius of a substrate coated with both A and B moieties be no greater than 90 percent of the bending radius of a substrate coated with only the A moiety.

The use of the B material allows one to produce a coated substrate with a springback angle of less than about 45 degrees. As is known to those skilled in the art, all

materials have a finite modulus of elasticity; thus, plastic deformation is followed by some elastic recovery when the load is removed. In bending, this recovery is called springback. See, e.g., page 462 of S. Kalparjian's "Manufacturing Engineering and Technology," Third Edition (Addison Wesley Publishing Company, New York, New York, 1995).

In one preferred embodiment, the B material is aluminum and the C material is nitrogen, whereby an AlN moiety is formed. Without wishing to be bound to any particular theory, applicants believe that aluminum nitride (and comparable materials) are both electrically insulating and thermally conductive, thus providing a excellent combination of properties for certain end uses.

Referring again to Figures 3 and 4, when an electromagnetic field 110 is incident upon the nanomagnetic material comprised of A and B (see Figure 3), such a field will be reflected to some degree depending upon the ratio of moiety A and moiety B. In one embodiment, it is preferred that at least 1 percent of such field is reflected in the direction of arrow 112 (see Figure 4). In another embodiment, it is preferred that at least about 10 percent of such field is reflected. In yet another embodiment, at least about 90 percent of such field is reflected. Without wishing to be bound to any particular theory, applicants believe that the degree of reflection depends upon the concentration of A in the A/B mixture.

Referring again to Figure 3, and in one embodiment, the nanomagnetic material is comprised of moiety A, moiety C, and optionally moiety B. The moiety C is preferably selected from the group consisting of elemental oxygen, elemental nitrogen, elemental carbon, elemental fluorine, elemental chlorine, elemental hydrogen, and elemental

helium, elemental neon, elemental argon, elemental krypton, elemental xenon, and the like. In one aspect of this embodiment, the C moiety is selected from the group consisting of elemental oxygen, elemental nitrogen, and mixtures thereof.

It is preferred, when the C moiety is present, that it be present in a concentration of from about 1 to about 90 mole percent, based upon the total number of moles of the A moiety and/or the B moiety and the C moiety in the composition.

Referring again to Figure 3, and in the embodiment depicted, the area 114 produces a composition which optimizes the degree to which magnetic flux are initially trapped and/or thereafter released by the composition when a magnetic field is withdrawing from the composition.

Without wishing to be bound to any particular theory, applicants believe that, when a composition as described by area 114 is subjected to an alternating magnetic field, at least a portion of the magnetic field is trapped by the composition when the field is strong, and then this portion tends to be released when the field lessens in intensity.

Thus, e.g., it is believed that, when the magnetic field 110 is applied to the nanomagnetic material, it starts to increase, in a typical sine wave fashion. After a specified period of time, a magnetic moment is created within the nanomagnetic material; but, because of the time delay, there is a phase shift.

The time delay will vary with the composition of the nanomagnetic material. By maximizing the amount of trapping, and by minimizing the amount of reflection and absorption, one may minimize the magnetic artifacts caused by the nanomagnetic shield.

Thus, and referring again to Figure 3, one may optimize the A/B/C composition to preferably be within the area 114. In general, the A/B/C composition has molar ratios

such that the ratio of A/(A and C) is from about 1 to about 99 mole percent and, preferably, from about 10 to about 90 mole percent. In one preferred embodiment, such ratio is from about 40 to about 60 molar percent.

The molar ratio of A/(A and B and C) generally is from about 1 to about 99 mole percent and, preferably, from about 10 to about 90 molar percent. In one embodiment, such molar ratio is from about 30 to about 60 molar percent.

The molar ratio of B/(A plus B plus C) generally is from about 1 to about 99 mole percent and, preferably, from about 10 to about 40 mole percent.

The molar ratio of C/(A plus B plus C) generally is from about 1 to about 99 mole percent and, preferably, from about 10 to about 50 mole percent.

In one embodiment, the composition of the nanomagnetic material is chosen so that the applied electromagnetic field 110 is absorbed by the nanomagnetic material by less than about 1 percent; thus, in this embodiment, the applied magnetic field 110 is substantially restored by correcting the time delay.

By utilizing nanomagnetic material that absorbs the electromagnetic field, one may selectively direct energy to various cells within a biological organism that are to be treated. Thus, e.g., cancer cells can be injected with the nanomagnetic material and then destroyed by the application of externally applied electromagnetic fields. Because of the nano size of applicants' materials, they can readily and preferentially be directed to the malignant cells to be treated within a living organism. In this embodiment, the nanomagnetic material preferably has a particle size of from about 5 to about 10 nanometers.

#### Other embodiments of the invention

In the remainder of this specification, certain other preferred embodiments of applicants' invention will be described.

In one embodiment, the composition of this invention is comprised of nanomagnetic particles with a specified magnetization. As is known to those skilled in the art, magnetization is the magnetic moment per unit volume of a substance. Reference may be had, e.g., to United States patents 4,169,998, 4,168,481, 4,166,263, 5,260,132, 4,778,714, and the like. The entire disclosure of each of these United States patents is hereby incorporated by reference into this specification.

In this embodiment, the nanomagnetic particles are present within a layer that preferably has a saturation magnetization, at 25 degrees Centigrade, of from about 1 to about 36,000 Gauss, or higher. In one embodiment, the saturation magnetization at room temperature of the nanomagnetic particles is from about 500 to about 10,000 Gauss. For a discussion of the saturation magnetization of various materials, reference may be had, e.g., to United States patents 4,705,613, 4,631,613, 5,543,070, 3,901,741 (cobalt, samarium, and gadolinium alloys), and the like. The entire disclosure of each of these United States patents is hereby incorporated by reference into this specification. As will be apparent to those skilled in the art, especially upon studying the aforementioned patents, the saturation magnetization of thin films is often higher than the saturation magnetization of bulk objects.

In one embodiment, it is preferred to utilize a thin film with a thickness of less than about 2 microns and a saturation magnetization in excess of 20,000 Gauss. The thickness of the layer of nanomagnetic material is measured from the bottom surface of the layer that contains such material to the top surface of such layer that contains such

material; and such bottom surface and/or such top surface may be contiguous with other layers of material (such as insulating material) that do not contain nanomagnetic particles.

Thus, e.g., one may make a thin film in accordance with the procedure described at page 156 of Nature, Volume 407, September 14, 2000, that describes a multilayer thin film that has a saturation magnetization of 24,000 Gauss.

By the appropriate selection of nanomagnetic particles, and the thickness of the films deposited, one may obtain saturation magnetizations of as high as at least about 36,000.

In one embodiment, the nanomagnetic materials used in the invention typically comprise one or more of iron, cobalt, nickel, gadolinium, and samarium atoms. Thus, e.g., typical nanomagnetic materials include alloys of iron and nickel (permalloy), cobalt, niobium, and zirconium (CNZ), iron, boron, and nitrogen, cobalt, iron, boron, and silica, iron, cobalt, boron, and fluoride, and the like. These and other materials are described in a book by J. Douglas Adam et al. entitled “Handbook of Thin Film Devices” (Academic Press, San Diego, California, 2000). Chapter 5 of this book, beginning at page 185, describes “magnetic films for planar inductive components and devices;” and Tables 5.1 and 5.2 in this chapter describe many magnetic materials.

In one embodiment, the nanomagnetic material has a saturation magnetization of from about 1 to about 36,000 Gauss. In one embodiment, the nanomagnetic material has a saturation magnetization of from about 200 to about 26,000 Gauss.

In one embodiment, the nanomagnetic material also has a coercive force of from about 0.01 to about 5,000 Oersteds. The term coercive force refers to the magnetic field,

$H$ , which must be applied to a magnetic material in a symmetrical, cyclically magnetized fashion, to make the magnetic induction,  $B$ , vanish; this term often is referred to as magnetic coercive force. Reference may be had, e.g., to United States patents 4,061,824, 6,257,512, 5,967,223, 4,939,610, 4,741,953, and the like. The entire disclosure of each of these United States patents is hereby incorporated by reference into this specification.

In one embodiment, the nanomagnetic material has a coercive force of from about 0.01 to about 3,000 Oersteds. In yet another embodiment, the nanomagnetic material 103 has a coercive force of from about 0.1 to about 10.

In one embodiment, the nanomagnetic material preferably has a relative magnetic permeability of from about 1 to about 500,000; in one embodiment, such material has a relative magnetic permeability of from about 1.5 to about 260,000. As used in this specification, the term relative magnetic permeability is equal to  $B/H$ , and is also equal to the slope of a section of the magnetization curve of the film. Reference may be had, e.g., to page 4-28 of E.U. Condon et al.'s "Handbook of Physics" (McGraw-Hill Book Company, Inc., New York, 1958).

Reference also may be had to page 1399 of Sybil P. Parker's "McGraw-Hill Dictionary of Scientific and Technical Terms," Fourth Edition (McGraw Hill Book Company, New York, 1989). As is disclosed on this page 1399, permeability is "...a factor, characteristic of a material, that is proportional to the magnetic induction produced in a material divided by the magnetic field strength; it is a tensor when these quantities are not parallel.

Reference also may be had, e.g., to United States patents 6,181,232, 5,581,224, 5,506,559, 4,246,586, 6,390,443, and the like. The entire disclosure of each of these United States patents is hereby incorporated by reference into this specification.

In one embodiment, the nanomagnetic material has a relative magnetic permeability of from about 1.5 to about 2,000.

In one embodiment, the nanomagnetic material preferably has a mass density of at least about 0.001 grams per cubic centimeter; in one aspect of this embodiment, such mass density is at least about 1 gram per cubic centimeter. As used in this specification, the term mass density refers to the mass of a give substance per unit volume. See, e.g., page 510 of the aforementioned "McGraw-Hill Dictionary of Scientific and Technical Terms." In another embodiment, the material has a mass density of at least about 3 grams per cubic centimeter. In another embodiment, the nanomagnetic material has a mass density of at least about 4 grams per cubic centimeter.

In one embodiment, it is preferred that the nanomagnetic material, and/or the article into which the nanomagnetic material has been incorporated, be interposed between a source of radiation and a substrate to be protected therefrom.

In one embodiment, the nanomagnetic material is in the form of a layer that preferably has a saturation magnetization, at 25 degree Centigrade, of from about 1 to about 36,000 Gauss. ( and, more preferably, from about 1 to about 26,000 Gauss). In one aspect of this embodiment, the saturation magnetization at room temperature of the nanomagnetic particles is from about 500 to about 10,000 Gauss.

In one embodiment, the nanomagnetic material is disposed within an insulating matrix so that any heat produced by such particles will be slowly dispersed within such

matrix. Such matrix may be made from, e.g., ceria, calcium oxide, silica, alumina, and the like. In general, the insulating material preferably has a thermal conductivity of less than about 20 (calories centimeters/square centimeters-degree Kelvin second) x 10,000. See, e.g., page E-6 of the 63<sup>rd</sup>. Edition of the "Handbook of Chemistry and Physics" (CRC Press, Inc. Boca Raton, Florida, 1982).

In one embodiment, there is provided a coating of nanomagnetic particles that consists of a mixture of aluminum oxide ( $\text{Al}_2\text{O}_3$ ), iron, and other particles that have the ability to deflect electromagnetic fields while remaining electrically non-conductive. In one aspect of this embodiment, the particle size in such a coating is approximately 10 nanometers. Preferably the particle packing density is relatively low so as to minimize electrical conductivity. Such a coating, when placed on a fully or partially metallic object (such as a guide wire, catheter, stent, and the like) is capable of deflecting electromagnetic fields, thereby protecting sensitive internal components, while also preventing the formation of eddy currents in the metallic object or coating. The absence of eddy currents in a metallic medical device provides several advantages, to wit: (1) reduction or elimination of heating, (2) reduction or elimination of electrical voltages which can damage the device and/or inappropriately stimulate internal tissues and organs, and (3) reduction or elimination of disruption and distortion of a magnetic-resonance image.

#### Determination of the heat shielding effect of the magnetic shield

In one preferred embodiment, the composition of this invention minimizes the extent to which a substrate increases its heat when subjected to a strong magnetic field. This heat buildup can be determined in accordance with A.S.T.M. Standard Test F-2182-

02, "Standard test method for measurement of radio-frequency induced heating near passive implant during magnetic resonance imaging."

In this test, the radiation used is representative of the fields present during MRI procedures. As is known to those skilled in the art, such fields typically include a static field with a strength of from about 0.5 to about 2 Teslas, a radio frequency alternating magnetic field with a strength of from about 20 microTeslas to about 100 microTeslas, and a gradient magnetic field that has three components (x, y, and z), each of which has a field strength of from about 0.05 to 500 milliTeslas.

During this test, a temperature probe is used to measure the temperature of an unshielded conductor when subjected to the magnetic field in accordance with such A.S.T.M. F-2182-02.

The same test is then performed upon a shielded conductor assembly that is comprised of the conductor and a magnetic shield.

The magnetic shield used may comprise nanomagnetic particles, as described hereinabove. Alternatively, or additionally, it may comprise other shielding material, such as, e.g., oriented nanotubes (see, e.g., United States patent 6,265,466).

In one embodiment, the shield is in the form of a layer of shielding material with a thickness of from about 10 nanometers to about 1 millimeter. In another embodiment, the thickness is from about 10 nanometers to about 20 microns.

In one preferred embodiment the shielded conductor is an implantable device and is connected to a pacemaker assembly comprised of a power source, a pulse generator, and a controller. The pacemaker assembly and its associated shielded conductor are preferably disposed within a living biological organism.

In one preferred embodiment, when the shielded assembly is tested in accordance with A.S.T.M. 2182-02, it will have a specified temperature increase ("dT<sub>s</sub>"). The "dT<sub>c</sub>" is the change in temperature of the unshielded conductor using precisely the same test conditions but omitting the shield. The ratio of dT<sub>s</sub>/dT<sub>c</sub> is the temperature increase ratio; and one minus the temperature increase ratio (1 – dT<sub>s</sub>/dT<sub>c</sub>) is defined as the heat shielding factor.

It is preferred that the shielded conductor assembly have a heat shielding factor of at least about 0.2. In one embodiment, the shielded conductor assembly has a heat shielding factor of at least 0.3.

In one embodiment, the nanomagnetic shield of this invention is comprised of an antithrombogenic material.

Antithrombogenic compositions and structures have been well known to those skilled in the art for many years. As is disclosed, e.g., in United States patent 5,783,570, the entire disclosure of which is hereby incorporated by reference into this specification, "Artificial materials superior in processability, elasticity and flexibility have been widely used as medical materials in recent years. It is expected that they will be increasingly used in a wider area as artificial organs such as artificial kidney, artificial lung, extracorporeal circulation devices and artificial blood vessels, as well as disposable products such as syringes, blood bags, cardiac catheters and the like. These medical materials are required to have, in addition to sufficient mechanical strength and durability, biological safety, which particularly means the absence of blood coagulation upon contact with blood, i.e., antithrombogenicity."

"Conventionally employed methods for imparting antithrombogenicity to medical materials are generally classified into three groups of (1) immobilizing a mucopolysaccharide (e.g., heparin) or a plasminogen activator (e.g., urokinase) on the surface of a material, (2) modifying the surface of a material so that it carries negative charge or hydrophilicity, and (3) inactivating the surface of a material. Of these, the method of (1) (hereinafter to be referred to briefly as surface heparin method) is further subdivided into the methods of (A) blending of a polymer and an organic solvent-soluble heparin, (B) coating of the material surface with an organic solvent-soluble heparin, (C) ionical bonding of heparin to a cationic group in the material, and (D) covalent bonding of a material and heparin."

"Of the above methods, the methods (2) and (3) are capable of affording a stable antithrombogenicity during a long-term contact with body fluids, since protein adsorbs onto the surface of a material to form a biomembrane-like surface. At the initial stage when the material has been introduced into the body (blood contact site) and when various coagulation factors etc. in the body have been activated, however, it is difficult to achieve sufficient antithrombogenicity without an anticoagulant therapy such as heparin administration."

Other antithrombogenic methods and compositions are also well known. Thus, by way of further illustration, United States published patent application 20010016611 discloses an antithrombogenic composition comprising an ionic complex of ammonium salts and heparin or a heparin derivative, said ammonium salts each comprising four aliphatic alkyl groups bonded thereto, wherein an ammonium salt comprising four aliphatic alkyl groups having not less than 22 and not more than 26 carbon atoms in total

is contained in an amount of not less than 5% and not more than 80% of the total ammonium salt by weight. The entire disclosure of this published patent application is hereby incorporated by reference into this specification.

Thus, e.g., United States patent 5,783,570 discloses an organic solvent-soluble mucopolysaccharide consisting of an ionic complex of at least one mucopolysaccharide (preferably heparin or heparin derivative) and a quaternary phosphonium, an antibacterial antithrombogenic composition comprising said organic solvent-soluble mucopolysaccharide and an antibacterial agent (preferably an inorganic antibacterial agent such as silver zeolite), and to a medical material comprising said organic solvent soluble mucopolysaccharide. The organic solvent-soluble mucopolysaccharide, and the antibacterial antithrombogenic composition and medical material containing same are said to easily impart antithrombogenicity and antibacterial property to a polymer to be a base material, which properties are maintained not only immediately after preparation of the material but also after long-term elution. The entire disclosure of this United States patent is hereby incorporated by reference into this specification.

By way of further illustration, United States patent 5,049,393 discloses anti-thrombogenic compositions, methods for their production and products made therefrom. The anti-thrombogenic compositions comprise a powdered anti-thrombogenic material homogeneously present in a solidifiable matrix material. The anti-thrombogenic material is preferably carbon and more preferably graphite particles. The matrix material is a silicon polymer, a urethane polymer or an acrylic polymer. The entire disclosure of this United States patent is hereby incorporated by reference into this specification.

By way of yet further illustration, United States patent 5,013,717 discloses a leach resistant composition that includes a quaternary ammonium complex of heparin and a silicone. A method for applying a coating of the composition to a surface of a medical article is also disclosed in the patent. Medical articles having surfaces that are both lubricious and antithrombogenic are produced in accordance with the method of the patent. The entire disclosure of this United States patent is hereby incorporated by reference into this specification.

A process for preparation of an iron-containing thin film

In one preferred embodiment of the invention, a sputtering technique is used to prepare an AlFe thin film as well as comparable thin films containing other atomic moieties, such as, e.g., elemental nitrogen, and elemental oxygen. Conventional sputtering techniques may be used to prepare such films by sputtering. See, for example, R. Herrmann and G. Brauer, "D.C.- and R.F. Magnetron Sputtering," in the "Handbook of Optical Properties: Volume I -- Thin Films for Optical Coatings," edited by R.E. Hummel and K.H. Guenther (CRC Press, Boca Raton, Florida, 1955). Reference also may be had, e.g., to M. Allendorf, "Report of Coatings on Glass Technology Roadmap Workshop," January 18-19, 2000, Livermore, California; and also to United States patent 6,342,134, "Method for producing piezoelectric films with rotating magnetron sputtering system." The entire disclosure of each of these prior art documents is hereby incorporated by reference into this specification.

Although the sputtering technique is advantageously used, the plasma technique described elsewhere in this specification also may be used. Alternatively, or additionally,

one or more of the other forming techniques described elsewhere in this specification also may be used.

One may utilize conventional sputtering devices in this process. By way of illustration and not limitation, a typical sputtering system is described in United States patent 5,178,739, the entire disclosure of which is hereby incorporated by reference into this specification. As is disclosed in this patent, "...a sputter system 10 includes a vacuum chamber 20, which contains a circular end sputter target 12, a hollow, cylindrical, thin, cathode magnetron target 14, a RF coil 16 and a chuck 18, which holds a semiconductor substrate 19. The atmosphere inside the vacuum chamber 20 is controlled through channel 22 by a pump (not shown). The vacuum chamber 20 is cylindrical and has a series of permanent, magnets 24 positioned around the chamber and in close proximity therewith to create a multiple field configuration near the interior surface 15 of target 12. Magnets 26, 28 are placed above end sputter target 12 to also create a multipole field in proximity to target 12. A singular magnet 26 is placed above the center of target 12 with a plurality of other magnets 28 disposed in a circular formation around magnet 26. For convenience, only two magnets 24 and 28 are shown. The configuration of target 12 with magnets 26, 28 comprises a magnetron sputter source 29 known in the prior art, such as the Torus-10E system manufactured by K. Lesker, Inc.. A sputter power supply 30 (DC or RF) is connected by a line 32 to the sputter target 12. A RF supply 34 provides power to RF coil 16 by a line 36 and through a matching network 37. Variable impedance 38 is connected in series with the cold end 17 of coil 16. A second sputter power supply 39 is connected by a line 40 to cylindrical sputter target 14. A bias power supply 42 (DC

or RF) is connected by a line 44 to chuck 18 in order to provide electrical bias to substrate 19 placed thereon, in a manner well known in the prior art."

By way of yet further illustration, other conventional sputtering systems and processes are described in United States patents 5,569,506 (a modified Kurt Lesker sputtering system), 5,824,761 (a Lesker Torus 10 sputter cathode), 5,768,123, 5,645,910, 6,046,398 (sputter deposition with a Kurt J. Lesker Co. Torus 2 sputter gun), 5,736,488, 5,567,673, 6,454,910, and the like. The entire disclosure of each of these United States patents is hereby incorporated by reference into this specification.

By way of yet further illustration, one may use the techniques described in a paper by Xingwu Wang et al. entitled "Technique Devised for Sputtering AlN Thin Films," published in "the Glass Researcher," Volume 11, No. 2 (December 12, 2002).

In one preferred embodiment, a magnetron sputtering technique is utilized, with a Lesker Super System III system. The vacuum chamber of this system is preferably cylindrical, with a diameter of approximately one meter and a height of approximately 0.6 meters. The base pressure used is from about 0.001 to 0.0001 Pascals. In one aspect of this process, the target is a metallic FeAl disk, with a diameter of approximately 0.1 meter. The molar ratio between iron and aluminum used in this aspect is approximately 70/30. Thus, the starting composition in this aspect is almost non-magnetic. See, e.g., page 83 (Figure 3.1aii) of R.S. Tebble et al.'s "Magnetic Materials" (Wiley-Interscience, New York, New York, 1969); this Figure discloses that a bulk composition containing iron and aluminum with at least 30 mole percent of aluminum (by total moles of iron and aluminum) is substantially non-magnetic.

In this aspect, to fabricate FeAl films, a DC power source is utilized, with a power level of from about 150 to about 550 watts (Advanced Energy Company of Colorado, model MDX Magnetron Drive). The sputtering gas used in this aspect is argon, with a flow rate of from about 0.0012 to about 0.0018 standard cubic meters per second. To fabricate FeAlN films in this aspect, in addition to the DC source, a pulse-forming device is utilized, with a frequency of from about 50 to about 250 MHz (Advanced Energy Company, model Sparc-le V). One may fabricate FeAlO films in a similar manner but using oxygen rather than nitrogen.

In this aspect, a typical argon flow rate is from about  $(0.9 \text{ to about } 1.5) \times 10^{-3}$  standard cubic meters per second; a typical nitrogen flow rate is from about  $(0.9 \text{ to about } 1.8) \times 10^{-3}$  standard cubic meters per second; and a typical oxygen flow rate is from about  $(0.5 \text{ to about } 2) \times 10^{-3}$  standard cubic meters per second. During fabrication, the pressure typically is maintained at from about 0.2 to about 0.4 Pascals. Such a pressure range is found to be suitable for nanomagnetic materials fabrications.

In this aspect, the substrate used may be either flat or curved. A typical flat substrate is a silicon wafer with or without a thermally grown silicon dioxide layer, and its diameter is preferably from about 0.1 to about 0.15 meters. A typical curved substrate is an aluminum rod or a stainless steel wire, with a length of from about 0.10 to about 0.56 meters and a diameter of from  $(\text{about } 0.8 \text{ to about } 3.0) \times 10^{-3}$  meters. The distance between the substrate and the target is preferably from about 0.05 to about 0.26 meters.

In this aspect, in order to deposit a film on a wafer, the wafer is fixed on a substrate holder. The substrate may or may not be rotated during deposition. In one embodiment, to deposit a film on a rod or wire, the rod or wire is rotated at a rotational

speed of from about 0.01 to about 0.1 revolutions per second, and it is moved slowly back and forth along its symmetrical axis with a maximum speed of about 0.01 meters per second.

In this aspect, to achieve a film deposition rate on the flat wafer of  $5 \times 10^{-10}$  meters per second, the power required for the FeAl film is 200 watts, and the power required for the FeAlN film is 500 watts. The resistivity of the FeAlN film is approximately one order of magnitude larger than that of the metallic FeAl film. Similarly, the resistivity of the FeAlO film is about one order of magnitude larger than that of the metallic FeAl film.

Iron containing magnetic materials, such as FeAl, FeAlN and FeAlO, may be fabricated by sputtering. The magnetic properties of those materials vary with stoichiometric ratios, particle sizes, and fabrication conditions; see, e.g., R.S. Tebble and D.J. Craik, "Magnetic Materials", pp. 81-88, Wiley-Interscience, New York, 1969. As is disclosed in this reference, when the iron molar ratio in bulk FeAl materials is less than 70 percent or so, the materials will no longer exhibit magnetic properties.

However, it has been discovered that, in contrast to bulk materials, a thin film material often exhibits different properties.

Figure 5 is a schematic sectional view, not drawn to scale, of a shielded conductor assembly 130 is comprised of a conductor 132 and, disposed around such conductor, a film 134 of nanomagnetic material. The conductor 132 preferably has a resistivity at 20 degrees Centigrade of from about 1 to about 100-microohm-centimeters.

The film 134 is comprised of nanomagnetic material that preferably has a maximum dimension of from about 10 to about 100 nanometers. The film 134 also

preferably has a saturation magnetization of from about 200 to about 26,000 Gauss and a thickness of less than about 2 microns. In one embodiment, the magnetically shielded conductor assembly 130 is flexible, having a bend radius of less than 2 centimeters. Reference may be had, e.g., to United States patent 6,506,972, the entire disclosure of which is hereby incorporated by reference into this specification.

As used in this specification, the term flexible refers to an assembly that can be bent to form a circle with a radius of less than 2 centimeters without breaking. Put another way, the bend radius of the coated assembly is preferably less than 2 centimeters. Reference may be had, e.g., to United States patents 4,705,353, 5,946,439, 5,315,365, 4,641,917, 5,913,005, and the like. The entire disclosure of each of these United States patents is hereby incorporated by reference into this specification.

Without wishing to be bound to any particular theory, applicants believe that the use of nanomagnetic materials in their coatings and their articles of manufacture allows one to produce a flexible device that otherwise could not be produced were not the materials so used nano-sized (less than 100 nanometers).

Referring again to Figure 5, and in the preferred embodiment depicted therein, one or more electrical filter circuit(s) 136 are preferably disposed around the nanomagnetic film 134. These circuit(s) may be deposited by conventional means.

In one embodiment, the electrical filter circuit(s) are deposited onto the film 134 by one or more of the techniques described in United States patents 5,498,289 (apparatus for applying narrow metal electrode), 5,389,573 (method for making narrow metal electrode), 5,973,573 (method of making narrow metal electrode), 5,973,259 (heated tool positioned in the X, Y, and Z-directions for depositing electrode), 5,741,557 (method for

depositing fine lines onto a substrate), and the like. The entire disclosure of each of these United States patents is hereby incorporated by reference into this specification.

Referring again to Figure 5, and in the preferred embodiment depicted therein, disposed around electrical filter circuit(s) 136 is a second film of nanomagnetic material 138, which may be identical to or different from film layer 134. In one embodiment, film layer 138 provides a different filtering response to electromagnetic waves than does film layer 134.

Disposed around nanomagnetic film layer 138 is a second layer of electrical filter circuit(s) 140. Each of circuit(s) 136 and circuit(s) 140 comprises at least one electrical circuit. It is preferred that the at least two circuits that comprise assembly 130 provide different electrical responses.

As is known to those skilled in the art, at high-frequencies the inductive reactance of a coil is great. The inductive reactance ( $X_L$ ) is equal to  $2\pi FL$ , wherein F is the frequency (in hertz), and L is the inductance (in Henries).

At low-frequencies, by comparison, the capacitative reactance ( $X_C$ ) is high, being equal to  $1/2\pi FC$ , wherein C is the capacitance in Farads. The impedance of a circuit, Z, is equal to the square root of  $(R^2 + [X_L - X_C]^2)$ , wherein R is the resistance, in ohms, of the circuit, and  $X_L$  and  $X_C$  are the inductive reactance and the capacitative reactance, respectively, in ohms, of the circuit.

Thus, for any particular alternating frequency electromagnetic wave, one can, by the appropriate selection of values for R, L, and C, pick a circuit that is purely resistive (in which case the inductive reactance is equal to the capacitative reactance at that frequency), is primarily inductive, or is primarily capacitative.

Maximum power transfer occurs at resonance, when the inductance reactance is equal to the capacitative reactance and the difference between them is zero. Conversely, minimum power transfer occurs when the circuit has little resistance in it (all circuits have some finite resistance) but is predominantly inductive or predominantly capacitative.

An LC tank circuit is an example of a circuit in which minimum power is transmitted. A tank circuit is a circuit in which an inductor and capacitor are in parallel; such a circuit appears, e.g., in the output stage of a radio transmitter.

An LC tank circuit exhibits the well-known flywheel effect, in which the energy introduced into the circuit continues to oscillate between the capacitor and inductor after an input signal has been applied; the oscillation stops when the tank-circuit finally loses the energy absorbed, but it resumes when a new source of energy is applied. The lower the inherent resistance of the circuit, the longer the oscillation will continue before dying out.

A typical tank circuit is comprised of a parallel-resonant circuit; and it acts as a selective filter. As is known to those skilled in the art, and as is disclosed in Stan Gibilisco's "Handbook of Radio & Wireless Technology" (McGraw-Hill, New York, New York, 1999), a selective filter is a circuit designed to tailor the way an electronic circuit or system responds to signals at various frequencies (see page 62).

The selective filter may be a bandpass filter (see pages 62-63 of the Gibilisco book) that comprises a resonant circuit, or a combination of resonant circuits, designed to discriminate against all frequencies except a specified frequency, or a band of frequencies between two limiting frequencies. In a parallel LC circuit, a bandpass filter shows a high

impedance at the desired frequency or frequencies and a low impedance at unwanted frequencies. In a series LC configuration, the filter has a low impedance at the desired frequency or frequencies, and a high impedance at unwanted frequencies.

The selective filter may be a band-rejection filter, also known as a band-stop filter (see pages 63-65 of the Gibilisco book). This band-rejection filter comprises a resonant circuit adapted to pass energy at all frequencies except within a certain range. The attenuation is greatest at the resonant frequency or within two limiting frequencies.

The selective filter may be a notch filter; see page 65 of the Gibilisco book. A notch filter is a narrowband-rejection filter. A properly designed notch filter can produce attenuation in excess of 40 decibels in the center of the notch.

The selective filter may be a high-pass filter; see pages 65-66 of the Gibilisco book. A high-pass filter is a combination of capacitance, inductance, and/or resistance intended to produce large amounts of attenuation below a certain frequency and little or no attenuation above that frequency. The frequency above which the transition occurs is called the cutoff frequency.

The selective filter may be a low-pass filter; see pages 67-68 of the Gibilisco book. A low-pass filter is a combination of capacitance, inductance, and/or resistance intended to produce large amounts of attenuation above a certain frequency and little or no attenuation below that frequency.

In the embodiment depicted in Figure 5, the electrical circuit is integrally formed with the coated conductor construct. In another embodiment, not shown in Figure 5, one or more electrical circuits are separately formed from a coated substrate construct and then operatively connected to such construct.

Figure 6A is a sectional schematic view of one preferred shielded assembly 131 that is comprised of a conductor 133 and, disposed around such conductor 133, a layer of nanomagnetic material 135.

In the embodiment depicted in Figure 6A, the layer 135 of nanomagnetic material preferably has a thickness 137 of at least 150 nanometers and, more preferably, at least about 200 nanometers. In one embodiment, the thickness of layer 135 is from about 500 to about 1,000 nanometers.

The layer 135 of nanomagnetic material 137 preferably is comprised of nanomagnetic material that may be formed, e.g., by subjecting the material in layer 137 to a magnetic field of from about 10 Gauss to about 40 Tesla for from about 1 to about 20 minutes. The layer 135 preferably has a mass density of at least about 0.001 grams per cubic centimeter (and preferably at least about 0.01 grams per cubic centimeter), a saturation magnetization of from about 1 to about 36,000 Gauss, and a coercive force of from about 0.01 to about 5,000.

In one embodiment, the B moiety is added to the nanomagnetic A moiety, preferably with a B/A molar ratio of from about 5:95 to about 95:5 (see Figure 3). In one aspect of this embodiment, the resistivity of the mixture of the B moiety and the A moiety is from about 1 micro-ohm-cm to about 10,000 micro-ohm-cm.

Without wishing to be bound to any particular theory, applicants believe that such a mixture of the A and B moieties provides two mechanisms for shielding the magnetic fields. One such mechanism/effect is the shielding provided by the nanomagnetic materials, described elsewhere in this specification. The other mechanism/effect is the shielding provided by the electrically conductive materials.

In one particularly preferred embodiment, the A moiety is iron, the B moiety is aluminum, and the molar ratio of A/B is about 70:30; the resistivity of this mixture is about 8 micro-ohms-cm.

Figure 6B is a schematic sectional view of a magnetically shielded assembly 139 that is similar to assembly 131 but differs therefrom in that a layer 141 of nanoelectrical material is disposed around layer 135.

The layer of nanoelectrical material 141 preferably has a thickness of from about 0.5 to about 2 microns. In this embodiment, the nanoelectrical material comprising layer 141 has a resistivity of from about 1 to about 100 microohm-centimeters. As is known to those skilled in the art, when nanoelectrical material is exposed to electromagnetic radiation, and in particular to an electric field, it will shield the substrate over which it is disposed from such electrical field. Reference may be had, e.g., to International patent publication WO9820719 in which reference is made to United States patent 4,963,291; each of these patents and patent applications is hereby incorporated by reference into this specification.

As is disclosed in United States patent 4,963,291 of Bercaw, one may produce electromagnetic shielding resins comprised of electroconductive particles, such as iron, aluminum, copper, silver and steel in sizes ranging from 0.5 to .50 microns. The entire disclosure of this United States patent is hereby incorporated by reference into this specification.

The nanoelectrical particles used in this aspect of the invention preferably have a particle size within the range of from about 1 to about 100 microns, and a resistivity of from about 1.6 to about 100 microohm-centimeters. In one embodiment, such

nanoelectrical particles comprise a mixture of iron and aluminum. In another embodiment, such nanoelectrical particles consist essentially of a mixture of iron and aluminum.

It is preferred that, in such nanoelectrical particles, and in one embodiment, at least 9 moles of aluminum are present for each mole of iron. In another embodiment, at least about 9.5 moles of aluminum are present for each mole of iron. In yet another embodiment, at least 9.9 moles of aluminum are present for each mole of iron.

In one embodiment, and referring again to Figure 6D, the layer 141 of nanoelectrical material has a thermal conductivity of from about 1 to about 4 watts/centimeter-degree Kelvin.

In one embodiment, not shown, in either or both of layers 135 and 141 there is present both the nanoelectrical material and the nanomagnetic material. One may produce such a layer 135 and/or 141 by simultaneously depositing the nanoelectrical particles and the nanomagnetic particles with, e.g., sputtering technology such as, e.g., the sputtering technology described elsewhere in this specification.

Figure 6C is a sectional schematic view of a magnetically shielded assembly 143 that differs from assembly 131 in that it contains a layer 145 of nanothermal material disposed around the layer 135 of nanomagnetic material. The layer 145 of nanothermal material preferably has a thickness of less than 2 microns and a thermal conductivity of at least about 150 watts/meter-degree Kelvin and, more preferably, at least about 200 watts/meter-degree Kelvin. It is preferred that the resistivity of layer 145 be at least about  $10^{10}$  microohm-centimeters and, more preferably, at least about  $10^{12}$  microohm-

centimeters. In one embodiment, the resistivity of layer 145 is at least about  $10^{13}$  microohm centimeters. In one embodiment, the nanothermal layer is comprised of AlN.

In one embodiment, depicted in Figure 6C, the thickness 147 of all of the layers of material coated onto the conductor 133 is preferably less than about 20 microns.

In Figure 6D, a sectional view of an assembly 149 is depicted that contains, disposed around conductor 133, layers of nanomagnetic material 135, nanoelectrical material 141, nanomagnetic material 135, and nanoelectrical material 141.

In Figure 6E, a sectional view of an assembly 151 is depicted that contains, disposed around conductor 133, a layer 135 of nanomagnetic material, a layer 141 of nanoelectrical material, a layer 135 of nanomagnetic material, a layer 145 of nanothermal material, and a layer 135 of nanomagnetic material. Optionally disposed in layer 153 is antithrombogenic material that is biocompatible with the living organism in which the assembly 151 is preferably disposed.

In the embodiments depicted in Figures 6A through 6E, the coatings 135, and/or 141, and/or 145, and/or 153, are disposed around a conductor 133. In one embodiment, the conductor so coated is preferably part of medical device, preferably an implanted medical device (such as, e.g., a pacemaker). In another embodiment, in addition to coating the conductor 133, or instead of coating the conductor 133, the actual medical device itself is coated.

Filter circuits that may be used with the coating constructs of the invention.

Many different electrical circuits, such as filter circuits, may be used in conjunction with the coating constructs of this invention. One such preferred filter circuit is illustrated in Figure 7.

In the filter circuit 150 depicted in Figure 7, a large coil 152 is chosen so that it generates a substantial amount of current 154 ( $I_T$ ) when exposed to the high-frequency electromagnetic wave produced during, e.g., an MRI process. This current 154 flowing in the direction of arrow 156 supplies energy to the resonant circuit 160 defined by capacitor 162, inductor 164, and load 166.

In the embodiment depicted in Figure 7, the load 166 is preferably a thermoelectric cooling device. As is known to those skilled in the art, thermoelectric cooling is cooling based upon the Peltier effect. An electric current is sent to a thermocouple whose cold junction is thermally coupled to a substrate to be cooled, while the hot junction dissipates heat to the surroundings. In the Peltier effect, heat is absorbed when current is sent through a junction of two dissimilar metals. See, e.g., page 1917 of the McGraw-Hill Dictionary of Scientific and Technical Terms, Fourth Edition (McGraw-Hill Book Company, New York, New York, 1989).

Thermoelectric coolers are often used to maintain a constant temperature; see, e.g., United States patents 5,313,333, 4,628,277, 5,347,869, 6,4445,487, 5,956,569, 5,930,430, 5,717,804; 5,596,228, 5,561,685, 6,240,113, 6,107,6390, and the like. The entire disclosure of each of these United States patents is hereby incorporated by reference into this specification.

By way of illustration and not limitation, United States patent 5,956,569 discloses an integrated thermoelectric cooler formed on the backside of a substrate. It appears that the device of this patent requires a direct current input; thus, one may utilize an appropriate D.C. power supply adapted to convert the alternating current to the required direct current.

From the foregoing, it will be apparent that, for each of the electromagnetic radiations produced during, e.g., a magnetic resonance imaging (MRI) process, one may utilize a series of energy-modifying devices to minimize the extent to which that particular electromagnetic radiation heats a particular substrate. Thus, e.g., one may convert much of the energy in the particular radiation into energy required to sustain a flywheel effect. Thus, e.g., one may absorb some of the energy (which will cause an increase in heat) and, with another portion of the energy, drive a thermoelectric cooler to cool the device, so that the net heat change is zero.

One may combine one or more selective filtering devices together with one or more of the nanomagnetic constructs of this invention to provide an assembly that is more effective in protecting against the adverse effects of high-frequency electromagnetic radiation than either device by itself. One such combined device is illustrated in Figure 8.

Figure 8 is a schematic of a magnetically shielded assembly 180 that is similar to the device depicted in Figure 1 of United States patent 4,745,923. The entire disclosure of such United States patent 4,745,923 is hereby incorporated by reference into this specification. This patent describes and claims: "An apparatus for protecting an implantable electrical device having a plurality of electrically conductive terminals, including output and return terminals and electrically conductive leads connected to said terminals against excessive currents comprising: means connected to form an electrically conductive low-impedance path for connection in circuit with at least one of said leads; means connected to form an electrically conductive high-impedance path for connection in circuit with said at least one lead; means for generating a signal representative of the current flowing in said low-impedance path; switch means for opening and closing said

low-impedance path; and means responsive to said signal representative of said current for controlling said switch means to open said low-impedance path when said current exceeds a predetermined level so that said current flows in said high-impedance path, whereby the current flowing into said electrical device is limited to a safe level."

As is disclosed in United States patent 4,745,923, "The invention disclosed herein relates generally to protection devices used to protect other devices from damage or destruction resulting from voltage or current surges. In particular, the present invention relates to such a protection device which is implantable in the body of a patient with a heart pacemaker to protect the pacemaker against current surges, particularly those resulting from the operation of an external or implanted heart defibrillator."

"It is well known that in many instances an implanted heart pacemaker can successfully regulate the otherwise faulty operation of a damaged or diseased heart. Generally, a typical pacemaker senses electrical activity or lack of such activity in the heart muscle, and supplies electrical stimulus pulses to the heart to stimulate contractions when necessary. The electrical stimulus pulses generated by a pacemaker, however, are ineffective to stop the lethal condition of fibrillation. However, it is well known that the application of a series of high-voltage pulses to the heart is often effective in arresting fibrillation. Of course it is desirable following defibrillation of the heart for the pacemaker to resume its normal regulatory role. A serious problem in this regard, however, is that without adequate protection against the large current flow induced by the application of high-voltage defibrillation pulses to the heart, a pacemaker can be damaged or destroyed. Obviously, from the standpoint of the patient's continued well being, this is a totally unacceptable consequence."

"In the past, a number of attempts have been made to provide adequate protection against excessive currents and voltages for pacemakers and other medical devices such as electrocardiogram (ECG) amplifiers. For example, it is known to connect one or more zener diodes between the opposite leads of a pacemaker to limit the voltage differential therebetween."

"However, as discussed in U.S. Pat. No. 4,320,763 to Money, this approach is not effective to limit the current flow between the heart tissue and the electrode at the distal end of the pacemaker lead. As a result, the heart tissue near the point of contact with the electrode can be severely damaged when high-voltage defibrillation pulses are applied to the heart. The U.S. Pat. No. 4,320,763 discloses that such tissue damage can be prevented by connecting a current limiting device such as a diode or a pair of field effect transistors (FETs) in series between a pacemaker output terminal and a distal electrode. However, it is apparent that the current limiting device thereby becomes a permanent part of the pacemaker circuit. When current limiting is not needed, for example during normal pacing operation, it is desirable to remove the current limiting device from the circuit to avoid unnecessary noise generation as well as loading effects."

"An approach for protecting the pacemaker circuitry itself is disclosed in U.S. Pat. No. 4,440,172 to Langer. The U.S. Pat. No. 4,440,172 discloses an implantable pacemaker and defibrillator unit in which the pacemaker and defibrillator share common output and return lines. The pacemaker generates negative-going stimulus pulses and is protected against the positive-going high-voltage defibrillator pulses by a resistor and forward biased diode connected in series between the common output line and ground. This approach only provides limited protection to the pacemaker from unidirectional

defibrillation pulses. Recent medical research has shown, however, that a number of benefits are obtained by using a bidirectional or "biphasic" pulse train to defibrillate the heart. Some of the benefits of "biphasic" defibrillation, which forms no part of the present invention, are discussed in Schuder, Defibrillation of 100 kg Calves With Asymmetrical, Bidirectional, Rectangular Pulses, *Cardiovascular Research* 419-426 (1984), and Jones, Decreased Defibrillator-Induced Dysfunction With Biphasic Rectangular Waveforms, *Am. J. Physiol.* 247 (Heart Circ. Physiol. 16): H792-H796 (1984)."

"...the present invention has as an object to provide a protection device that protects both a pacemaker or other implantable device and the heart tissue near a lead thereof against damage from high current and voltage levels...."

Referring again to Figure 8, and in the preferred embodiment depicted therein, a heart pacemaker 182 implanted in the body of a patient is electrically connected in circuit with the patient's heart 184 via conventional electrically conductive pacing/sensing and return leads 186/188. Pacing/sensing lead 186 contains an electrically conductive barbed or screw-shaped pacing/sensing electrode 190 at its distal end for making firm electrical contact with the heart 184. Return lead 188 contains at its distal end a conductive patch 192 which may be sewn to the wall of the heart 184 to ensure a solid electrical connection. Electrically connected between the pacing/sensing and return leads 186,188 are oppositely polled first and second zener diodes 194, 196 to limit the voltage differential between the terminals of the pacemaker 182. First zener diode 194 preferably limits the positive voltage differential to approximately +3 volts. Second zener diode 196 preferably limits the negative differential to approximately -10 volts. A protection circuit

198 is implanted with the pacemaker 182 and is electrically connected in series with return lead 188 and patch 192 between the heart 184 and the pacemaker 182.

In addition, a defibrillator 200, which may be either an external or an implanted unit, is also electrically connected in circuit with the heart 184. If implanted, the defibrillator 200 is electrically connected to the heart 184 via conventional electrically conductive output and return leads 202,204. Output lead 202 has attached to its distal end a conductive patch 206 which may be sewn to the wall of the heart 184. In this embodiment, return lead 204 is electrically connected at its distal end by any suitable means to return lead 188 between the heart 184 and the protection circuit 198 so that the pacemaker 182 and the defibrillator 200 share a common return lead to some extent. Of course, if the defibrillator 200 is an external unit, then no direct connections to the heart 184 are present. Instead, electrically conductive paddles of a type well known to those skilled in the art are supplied externally to the chest of a patient in the vicinity of the heart 184 as output and return electrodes.

The pacemaker 182 and defibrillator 200 described above are exemplary devices only and that the protection circuit 198 comprising a presently preferred embodiment of the present invention will find use in many other applications where protection of a device against high voltages and currents is desirable.

As is illustrated in FIG. 2 of United States patent 4,745,923 (the entire disclosure of which is hereby incorporated by reference into this specification), the protection circuit 16 is electrically connected to conductive patch 15 via return lead 13. In series with return lead 13 are a first and a second field effect transistor (FET) 22, 23 and a 5 ohm sensing resistor 24. The drain of the second FET 23 connects to return lead 13 on the

heart 11 side. The source of the second FET 23 connects to one end of the sensing resistor 24 and the source of the first FET 22 connects to the opposite end. The drain of the first FET 16 connects to the opposite end of return lead 13 on the pacemaker 10 side. The gates of the first and second FETs 22,23 are connected in parallel to one end of a 390K ohm current limiting resistor 29 and to the collectors of first and second parallel bipolar transistors 25,26. The other end of the 390K ohm current limiting resistor 29 connects to a DC voltage source 30.

In one preferred embodiment, illustrated in Figure 8, one or more of the pacemaker 182, the defibrillator 200, the leads 186 and 188, the protection circuit 198, the leads 202 and 204, and the patches 192 and 206 are coated with film 134 of nanomagnetic material (see Figure 5). This is indicated by the use of "(134)" after the element in question. Thus, e.g., "186(134)" indicates that lead 186 is coated with nanomagnetic film 134.

In another embodiment, not shown, one or more of the pacemaker 182, the defibrillator 200, the leads 186 and 188, the protection circuit 198, the leads 202 and 204, and the patches 192 and 206 are coated with film (not shown) that is comprised of nanomagnetic material and, optionally, one or more dielectric material, insulative material, thermal material, etc. Thus, e.g., one or more of the one or more of the pacemaker 182, the defibrillator 200, the leads 186 and 188, the protection circuit 198, the leads 202 and 204, and the patches 192 and 206 may be coated with one or more of the constructs illustrated in Figures 5 and/or 6A through 6E.

Referring again to the preferred embodiment depicted in Figure 8, the film 134 that is disposed about one or more of the components of the assembly 180 is preferably

comprised of at least about 30 weight percent of nanomagnetic material with a mass density of at least about 0.01 grams per cubic centimeter, a saturation magnetization of from about 1 to about 36,000 Gauss, a coercive force of from about 0.01 to about 5,000 Oersteds, a relative magnetic permeability of from about 1 to about 500,000, and an average particle size of less than about 100 nanometers

United States patent 4,745,923 discloses but one type of current-limiting protection circuit that may be used in the assembly 180 of Figure 8. One may use other such protection circuits disclosed in the prior art.

Thus, by way of illustration and not limitation, United States patent 4,320,763 discloses a device for preventing tissue damage when high-currents flow through the tissue as a result of high voltage differentials. The patent claims: "In a pacemaker assembly comprising pulse-generator means for generating electrical pulses and electrode means having a proximal end coupled to said pulse-generating means and a distal end designed to be placed adjacent to body tissue for delivering said pulses to said tissue, the improvement comprising: current-limiting means coupled in series with said pulse-generating means and said electrode means for permitting passage of said electrical pulses to said tissue and for protecting said tissue against tissue damaging current flow between said distal end of said electrode means and said tissue as may occur with cardioversion."

The object of the invention claimed in United States patent 4,320,763 was set forth in column 1 of the patent, wherein it was stated that: "It is therefore an object of the present invention to protect the heart tissue of a pacemaker implantee from damage upon

application of high voltages to the user's body." The entire disclosure of this United States patent is hereby incorporated by reference into this specification.

By way of further illustration, United States patent 5,197,468 discloses a "device for protecting an electronic prosthesis from adverse effects of RF...energy." This device includes "...a Ferrite body electrically and thermally connected to the lead wire and to a ground element." In particular, United States patent 5,197,468 discloses and claims: "an electronic prosthesis that is implantable into a user's body including: A) an electronic device that is implantable into a user's body and includes a dc power source, electronic control elements, tissue stimulating elements and an electronic lead wire electrically connecting said power source, said electronic control elements and said tissue stimulating elements; and B) a protective device for protecting said electronic device from undesired RF energy induced operation and from undesired electrostatic energy induced operation, said protective device including (1) a ground element having a first impedance and electrically separated from said lead wire by said first impedance, and (2) an impedance element in said lead wire connected between said dc power source and said tissue stimulating elements having an impedance that is greater than said first impedance when exposed to RF energy." The entire disclosure of this United States patent is hereby incorporated by reference into this specification.

As is disclosed in column 3 of United States patent 5,197,468, "...such external influences as RF energy...have been identified as causing problems with artificial cardiac pacers....The literature is replete with examples of cardiac pacer malfunctions traced to...MRI techniques...."

By way of further illustration, United States patent 5,584,870 discloses a device for protecting a cochlear implant from external electrostatic charges. The entire disclosure of this United States patent is hereby incorporated by reference into this specification.

By way of further illustration, United States patent 5,833,710 provides a device for protecting cardiac tissue near low energy implanted electrodes; the entire disclosure of this United States patent is hereby incorporated by reference into this specification. There is disclosed and claimed in this patent: " An implantable medical device comprising: an electronic circuit operable to provide low energy cardiac tissue stimulation and detection and at least two inputs to receive respectively, at least two low energy stimulation and detection electrodes, wherein the electronic circuitry has a reference potential as a system ground which is isolated from an earth ground; and an automatic, unidirectional current limiting circuit interposed in series between said electronic circuitry and each input and coupled to said reference potential, said automatic unidirectional current limiting circuitry having a protected output connected to said electronic circuitry and an unprotected input."

As is disclosed in column 3 of United States patent 5,833,710, "...the present invention pertains to protecting the circuitry connected to the low energy leads, and protecting the patient's tissue at the low energy lead sites, from the high energy pulses...and from high energy pulses from other medical electronic devices...."

By way of yet further illustration, United States patent 5,591,218 describes a "current limiter for implantable electronic device lead" which, like the device of United States patent 5,833,710, "...protects cardiac tissue near the low energy electrodes" (see

the abstract); the entire disclosure of this United States patent 5,591,218 is hereby incorporated by reference into this specification. This patent discloses and claims: " A unidirectional current limiting circuit for use in series with the lead of an implanted medical device having low energy stimulation and detection electrodes, comprising: an unprotected input and a protected output; a current flow from the unprotected input to the protected output; a reference potential corresponding to a ground potential; a bias voltage; a first switch having an open circuit condition, a current limiting condition, and a closed circuit condition, the first switch having an input connected to the unprotected input and an output; a low value resistor connected to the output of the first switch producing a first voltage in response to said current flow through the first switch; a second switch having an open circuit condition and a closed circuit condition the second switch being operatively connected between the bias voltage and the protected output; a voltage divider connected to the unprotected input and the protected output, said voltage provider and producing a control voltage corresponding to a voltage across the unprotected input and the protected output; and a voltage clamp circuit connected between the reference potential and the protected output and operable to maintain the protected output voltage within a preset voltage range of the reference voltage; wherein the first switch is biased in the closed circuit condition when the voltage of the low value resistor is below the bias voltage by a first predetermined amount, the first switch is biased in the current limiting condition when the voltage of the low value resistor is not below the bias voltage by the first predetermined amount, and wherein the second switch is automatically biased in the open circuit condition when the control voltage is less than a second predetermined amount and in the closed circuit condition when the control

voltage is greater than the second predetermined amount, the second switch closed circuit condition effectively lowering the bias voltage to place and maintain the first switch in the open circuit condition."

By way of yet further illustration, one may use the "current limiter for an implantable cardiac device disclosed in United States patent 6,161,040, the entire disclosure of which is hereby incorporated by reference into this specification. This patent describes and claims: "A defibrillator for implantation into a patient to provide therapy to a patient's heart, comprising: a pulse generator generating selectively defibrillation pulses, said defibrillation pulses having positive and negative phases; defibrillator electrodes for delivering said defibrillation pulses to said heart; first and sensing electrodes extending to said heart; a sensing circuit sensing intrinsic activity within said heart; and a protection circuit arranged between sensing electrodes and said sensing circuit to protect said sensing circuit from an overvoltage resulting from said defibrillation pulses, said protection circuit including a first section and a second section; wherein said first section and a second section each include an electronic element arranged to limit current during said positive phase and said negative, respectively; and a biasing circuit disposed in said protection circuit and shared by said first and second sections for biasing said electronic elements." As is disclosed in column 1 of United States patent 6,161,040, "...because the impedance of the heart tissues through which the shocks are discharged are unknown, it is difficult to control the current delivered through the shocks. Abnormally high current levels are undesirable because a high current may damage the heart tissues."

Referring again to Figure 8, and in the preferred embodiment depicted therein, it will be seen that the assembly 180 is comprised of one or more cancellation circuits 210 and/or 212. These cancellation circuitries 210,212, in one embodiment, are not connected to any other circuitry or device. Alternatively, the circuits 210/212 may be connected to each other (via line 214) and/or to the protection circuit 198 (via line 216) and/or to lines 186, and/or 202 and/or 204 (via line 218), and/or to defibrillator 206 and/or to heart 184. Other possible circuit arrangements will be apparent to those skilled in the art.

The cancellation circuits 210 and 212 preferably minimize the effects of high frequency electromagnetic radiation by the mechanism of cancellation. Cancellation is the elimination of one quantity by another, as when a voltage is reduced to zero by another voltage of equal magnitude and opposite sign. See, e.g., page 91 of Stan Gibilisco's "The Illustrated Dictionary of Electronics," Sixth Edition (Tab Books, Blue Ridge Summit, Pa., 1994).

One may use one or more of the cancellation circuits disclosed in the prior art, or variations thereof especially adapted to cancel the high-frequency electromagnetic waves present in a biological organism during MRI analyses. Some of these prior art cancellation circuits are discussed below.

United States patent 3,720,941 discloses a clutter cancellation circuit used in a monopulse radar system. This clutter cancellation circuit comprises: "...a. means for deriving first and second signals respectively indicative of first and second reception lobe responses of a monopulse antenna; first and second channels respectively coupled to said first and second signals; signal combining means for algebraically combining the signals

in said first and second channels, for providing a difference signal indicative of the algebraic difference of the signals in the said first and second channels, whereby a clutter cancelled output is provided when the phase and amplitude differences between the signals in said first and second channels are nulled; phase shifting means connected in series in said first channel for nulling the phase difference of the signals in said first and second channels; and amplitude adjusting means connected in said first channel for nulling the amplitude difference between the signals in said first and second channels."

The entire disclosure of this United States patent is hereby incorporated by reference into this specification.

United States patent 3,935,533 discloses a microwave transceiver comprised of a cancellation circuit. As is disclosed in claim 1 of this patent, the single oscillator microwave receiver comprises: "antenna means for transmitting and receiving microwave energy; means for coupling energy from said oscillator to said antenna means for transmission thereby, and for simultaneously coupling energy received at said antenna means and a small portion of the energy of said oscillator in mixed fashion to the input of said FM receiver; an AFC circuit connected to the output of said FM receiver; means for providing a substantially DC voltage suitable for controlling the carrier frequency of said microwave oscillator; summing means, the output of said summing means being connected to said frequency-controlling voltage input of said microwave oscillator; input means for applying transmitter input modulation to one input of said summing means; and first selectively operable means for connecting said AFC circuit or carrier voltage means to a second input of said summing means, alternatively, whereby said microwave oscillator provides a carrier frequency selectively determined by said AFC circuit or by

· said carrier voltage means, which is frequency modulated in accordance with said transmitter input modulation; wherein said input means includes a variable gain amplifier having a signal input and a gain control input, said signal input being connected to transmitter input modulation, the output of said variable gain amplifier being connected to the first input of said summing means; delay means responsive to transmitter input modulation for providing delayed transmitter input modulation which is delayed by a period of time substantially equal to the circuit signal propagation time from the input of said variable gain amplifier through said FM receiver; second selectively operable means responsive to the output of said FM receiver and to the output of said delay means for selectively combining said delayed transmitter input modulation with the output of said FM receiver in a voltage polarity relationship to provide a receiver output signal having transmitter input modulation substantially cancelled therefrom; and means responsive to said receiver output signal and to said delayed transmitter input modulation for providing a gain control signal to the gain control input of said variable gain amplifier, said gain control signal adjusting the gain of said variable gain amplifier so that the magnitude of transmitter input modulation included in the output of said FM receiver is adjusted with respect to the magnitude of delayed transmitter input modulation provided by said delay unit so that the transmitter input modulation in said receiver output signal is substantially nulled to zero." The entire disclosure of this United States patent is hereby incorporated by reference into this specification."

United States patent 4,535,476 discloses an offset geometry, interference canceling receiver that comprises: antenna means for receiving signals from a desired signal source and from an interference signal source located adjacent to the desired signal

source, said antenna means comprising a main feedhorn which is focused on said desired signal source and an auxiliary feedhorn which is focused on said interference signal source, the antenna means being responsive to signals from the desired signal source for generating a composite signal including a desired message signal and a first interference signal, the antenna means also being responsive to signals from the interference signal source for generating a second interference signal comprising the first interference signal, combining means including a first feedback control circuit responsive to a representation of the desired message signal for generating appropriate control signals to cause variations of the phase and amplitude of the first interference signal, means responsive to the control signals for adjusting the phase and amplitude of the first interference signal, and a combiner for combining the adjusted first interference signal with the composite signal to generate said representation of the desired message signal, and signal translation means including a first duplexer coupled to the antenna means for interfacing the composite signal received therefrom, a first amplifier means for adjusting the amplitude of the composite signal to a predetermined level, a second duplexer coupled to the antenna means for interfacing the second interference signal received therefrom, and a second amplifier means for adjusting the amplitude of the second interference signal to a predetermined level. The entire disclosure of this United States patent is hereby incorporated by reference into this specification.

United States patent 4,698,634 discloses a subsurface insection radar signal comprised of a clutter cancellation circuit. As is disclosed in claim 1 of this patent, the clutter cancellation circuit is comprised of "...clutter cancellation means operatively connected to said receiver means for eliminating internal reflections developed in said

system to prevent interference by said internal reflections with the desired external reflections to enhance the system detection capability and reliability of evaluation of said external reflections, said internal reflections comprising signals generated within said system by said antenna means, said transmitter means and said receiver means." The entire disclosure of this United States patent application is hereby incorporated by reference into this specification.

United States patent 5,280,290 discloses a self-oscillating mixer circuit that comprises "cancellation means for combining the IF signal with the modulating signal to cancel from the IF signal a modulation corresponding to that of the modulated RF signal, said cancellation means including a first input coupled to the output of the mixer, a second input for receiving the modulating signal, and an output for producing a demodulated signal." The entire disclosure of this United States patent is hereby incorporated by reference into this specification.

United States patent 5,407,027 also discloses a "...cancellation circuit for canceling offset voltage by storing, when said inverter is stopped while said current command generating circuit keeps generating the current command value, the output signal of said current detector, and by adding, when the inverter is in operation, the stored output signal to the present output signal of the current detector." The entire disclosure of this United States patent is hereby incorporated by reference into this specification.

United States patent 6,008,760 discloses a cancellation system for frequency reuse in microwave communications. This patent discloses and claims: ". A free-space electromagnetic wave communications system for canceling co-channel interference and transmit signal leakage, said communications system transmitting a plurality of signals

from at least one transmit location to at least one receive location, said communications system utilizing spatial gain distribution processing of the transmitted signals for providing frequency-reuse of the transmitted signals, utilizing distributed frequency compensation for compensating for frequency dependent variations of transmitted and received antenna beam patterns, utilizing interferometric beam-shaping for controlling beamwidth of antenna beam patterns, and utilizing interference cancellation for reducing transmit signal leakage in received signals, said communications system comprising: a signal transmitter located at the transmit location for transmitting a plurality of transmission signals, each of said transmission signals having a predetermined spatial gain distribution at the receive location, an antenna array comprising a plurality of spatially-separated antenna elements located at the receive location, each of said antenna elements being responsive to at least one of said transmission signals for generating a desired receive communications signal and being responsive to one or more said transmission signals for generating a noise signal, a cancellation circuit coupled to each of said plurality of antenna elements for receiving said desired communications signals and said noise signals, said cancellation circuit providing weights to said desired communications signals and said noise signals wherein said weights are determined from said spatial gain distribution of said transmission signals, said cancellation circuit combining said weighted noise and desired communications signals for canceling said noise signals, thereby separating said communications signals from said noise signals, an excitation means coupled to said antenna elements for generating a predetermined distribution of excitation signals to electrically excite said antenna elements for producing a predetermined beam pattern, the excitation signals having distributed

frequency characteristics, a transmit beam-shaping processor coupled to said excitation means for providing a frequency-dependent weight distribution to the excitation signals with respect to signal frequency such that a plurality of frequency-dependent beam patterns is generated by said array, each of the beam patterns corresponding to one of a plurality of different excitation signal frequencies, the beam patterns being substantially equal within a predetermined spatial region, a receiver coupled to said antenna elements for providing a predetermined weight distribution to the receive signals, the weighted receive signals being summed to provide a beam pattern that indicates responsiveness to the incident radiation with respect to an angle of incidence of the incident radiation, a receive beam-shaping processor coupled to said antenna elements for providing a frequency-dependent weight distribution to the receive signals with respect to receive signal frequency to produce a plurality of frequency-dependent beam patterns, each of the beam patterns corresponding to one of a plurality of different receive signal frequencies, the beam patterns being substantially equal within a predetermined spatial region, an interferometric receive beam-shaping processor coupled to said receiver for providing a plurality of weight distributions to the receive signals for providing a plurality of interfering receive beam patterns, the receive beam patterns being combined to produce a combined interferometric receive beam pattern, the combined interferometric receive beam pattern providing a predetermined receiver response in at least one direction, an interferometric transmit beam-shaping processor coupled to said excitation means for providing a plurality of weight distributions to the excitation signals for providing a plurality of interfering transmit beam patterns, the beam patterns being combined to produce a combined interferometric transmit beam pattern, the combined interferometric

transmit beam pattern providing a predetermined transmit signal profile in at least one direction, and an isolator circuit coupled between said excitation means, said antenna array, and said receiver, for electrically isolating said receiver from said excitation means, said isolator circuit comprising: an active branch, said active branch comprising an active reference branch coupled to a splitting circuit for receiving a reference signal, and a transmit branch, said transmit branch comprising a transmit input port for receiving an input transmit signal, a splitting circuit coupled to the input port for splitting the input transmit signal into an output transmit signal and a reference signal, and an output transmit port coupled to an antenna for conducting the output transmit signal to the antenna, a reference sensing element coupled to said active reference branch, said reference sensing element being responsive to the reference signal in said active reference branch, a transmit sensing element coupled to said transmit branch, said transmit sensing element being responsive to the output transmit signal and a receive signal generated by said antenna in response to incident electromagnetic radiation, a combining circuit coupled to said reference sensing element and said transmit sensing element for combining the responses of said reference sensing element and said transmit sensing element for canceling the reference sensing element response to the reference signal and the transmit sensing element response to the output transmit signal, said combining circuit having an output port for coupling the response of said transmit sensing element to the receive signal to a receiver, a passive reference branch coupled to said splitting circuit for receiving the second reference signal, said passive reference branch comprising a reference splitting circuit coupled to a dummy reference branch and a dummy antenna branch, said reference splitting circuit splitting the second reference signal into a dummy

reference branch signal and a dummy transmit signal, the dummy reference branch signal being coupled into said dummy reference branch, said dummy reference branch having a complex impedance that is proportional to the complex impedance of said active reference branch, and the dummy transmit signal being coupled into said dummy antenna branch, said dummy antenna branch comprising a variable impedance element, said dummy antenna branch having an impedance that is proportional to the impedance of said transmit branch, an injection circuit coupled between said combining circuit and said dummy antenna branch for injecting the receive signal at the output port of said combining circuit into said second reference branch, a control-signal generator coupled to said active signal branch and said passive reference branch, said control-signal generator being responsive to electrical signals in said active signal branch and said passive reference branch for generating a difference signal therefrom, the difference signal representing differences in the proportion of the complex impedance of said active signal branch to the complex impedance of said passive reference branch, and an impedance controller coupled between said control-signal generator and said variable impedance element for receiving the difference signal and adjusting the impedance of said variable impedance element in order to minimize the difference signal." The entire disclosure of this United States patent is hereby incorporated by reference into this specification.

United States patent 6,211,671 discloses a cancellation circuit that removes interfering signals from desired signals in electrical systems having antennas or other electromagnetic pickup systems. This patent claims: An electromagnetic receiver system adapted to receive and separate at least one desired electromagnetic transmission signal from at least one interfering electromagnetic transmission signal, the receiver system

including: a plurality of electromagnetic receivers adapted to be responsive to the at least one transmitted desired electromagnetic signal and the at least one transmitted interfering electromagnetic signal, the receivers generating a plurality of receive signals, each of the receive signals including at least one desired signal component and at least one interfering signal component, the receivers being spatially separated to receive different proportions of the at least one transmitted desired electromagnetic signal and the at least one transmitted interfering electromagnetic signal and a canceller coupled to the receivers adapted to process the receive signals, the canceller including an amplitude-adjustment circuit adapted to provide amplitude adjustment to at least one of the receive signals to compensate for amplitude differences between the at least one interfering signal component in each of a plurality of the receive signals resulting from at least one of a) differences in propagation of the at least one transmitted interfering signal to the plurality of electromagnetic receivers, and b) differences in the responsiveness of the electromagnetic receivers to the at least one transmitted interfering signal, the canceller including a phase-adjustment circuit adapted to provide phase adjustment to at least one of the receive signals to compensate for phase differences between the at least one interfering signal component in each of a plurality of the receive signals resulting from at least one of: a) differences in propagation of the at least one transmitted interfering signal to the plurality of electromagnetic receivers, and b) differences in the responsiveness of the electromagnetic receivers to the at least one transmitted interfering signal, the canceller adapted to combine the receive signals to separate at least one of the desired signal components by canceling at least one of the interfering signal components." The

entire disclosure of this United States patent is hereby incorporated by reference into this specification.

United States patent 6,348,791 discloses an electromagnetic transceiver in which a cancellation circuit removes interfering signals. This patent claims: "1. An electromagnetic transceiver capable of simultaneously transmitting and receiving electromagnetic signals, the transceiver including: an antenna system capable of transmitting and receiving the electromagnetic signals, a signal transmitter coupled to the antenna system, the transmitter adapted to couple electromagnetic signals to the antenna system for transmission, a receiver coupled to the antenna system, the receiver adapted to be responsive to the transmitted electromagnetic signals and electromagnetic signals received by the antenna system, a cancellation circuit coupled to the transmitter and to the receiver, the cancellation circuit adapted to couple at least one cancellation signal to the receiver that reduces the responsiveness of the receiver to the transmitted signals, the cancellation circuit characterized by at least one of: an amplitude-adjustment circuit adapted to compensate for amplitude differences between the at least one cancellation signal and the receiver response to the transmitted signals resulting from at least one of: a) differences in propagation between the transmitted signals and the at least one cancellation signal to the receiver, and b) differences in the responsiveness of the receiver to the transmitted signals and the at least one cancellation signal, and a phase-adjustment circuit adapted to compensate for phase differences between the at least one cancellation signal and the receiver response to the transmitted signals resulting from at least one of: a) differences in propagation between the transmitted signals and the at least one cancellation signal to the receiver, and b) differences in the responsiveness of the receiver

to the transmitted signals and the at least one cancellation signal." The entire disclosure of this United States patent is hereby incorporated by reference into this specification.

It will be apparent that not every component, or every circuit, or every device of these patents will be suitable for use in the cancellation circuitry 210 and/or the cancellation circuitry 212. What will also be apparent is that many of these components, devices, and circuits, and the principles on which they operate, will be suitable for use in cancellation circuitry 210,212, taking into account the high-frequency MRI electromagnetic waves such circuitry is preferably designed to cancel and the goal of minimizing the amount of heat produced by such MRI electromagnetic waves. In particular, many of these components, devices, and/or circuits, and the principles on which they operate, will be suitable for modifying the current flow through biological tissue with which the medical device is contiguous or near to.

Thus, in one embodiment, the applicants provide a magnetically shielded assembly comprised of a medical device implanted in a biological organism, wherein said medical device is disposed near biological tissue, wherein said magnetically shielded assembly is comprised of a nanomagnetic coating (such as, e.g., coating 134) disposed on at least a portion of said medical device, wherein said magnetically shielded assembly is further comprised of means for limiting the flow of current through said biological tissue, and wherein said nanomagnetic coating has the properties described elsewhere in this specification.

In general, the cancellation circuitry 210,212, and the rest of the devices depicted in Figure 8, will enable one to follow the process depicted in Figure 9.

Referring to Figure 9, and in step 240 thereof, the high-frequency electromagnetic waves produced during the MRI analyses are selectively received by the cancellation circuitry assemblies 210 and/or 212 by means of antennas 230 and 232 (see Figure 8).

As is disclosed at page 110 of Stan Gibilisco's "Handbook of Radio and Wireless Technology," Sixth Edition, *supra*, "...an antenna is a...transducer.... A receiving antenna converts an electromagnetic field (EM) into an alternating current(AC)."

The antennas 232,232 are preferably tuned antennas that, with the appropriate combinations of antenna length, inductance, and/or capacitance, produce the maximum amount of AC current at the high frequencies produced during MRI analyses. Tuned antennas are well known to those skilled in the art. Reference may be had, e.g., to United States patents 6,310,346 (wavelength-tunable coupled antenna), 5,999,138 (switched diversity antenna system), 6,496,153 (magnetic-field sending antenna with RLC circuit), 5,614,917 (RF sail pumped tuned antenna), 5,528,251 (double tuned dipole antenna), 5,241,160, 5,231,355 (automatically tuned antenna), 4,984,296 (tuned radio apparatus), 4,739,516 (frequency tuned antenna assembly), 4,660,039, 4,450,588 4,280,129 (variable mutual inductance tuned antenna), 4,194,154, 3,571,716 (electronically tuned antenna), and the like. The entire disclosure of each of these United States patents is hereby incorporated by reference into this specification.

Referring again to Figure 9, and in the preferred process depicted therein, in step 242, an alternating current is produced by the interaction of one or both of the antennas 230,232 with the high-frequency electromagnetic waves 273 (see Figure 8). This alternating current is then distributed to several different locations.

A portion of the alternating current is fed via line 244 to a power supply (not shown), which converts the alternating current to direct current in step 246. Thereafter, the direct current so produced is preferably fed via line 250 to a thermoelectric cooling assembly (such as the Peltier device cooling assembly 166 depicted in Figure 7), and in step 252 thermoelectric cooling is produced.

Referring again to Figure 9, and in the preferred process depicted therein, another portion of the alternating current produced in step 242 is fed via 254 to a wave generator (not shown), and in step 256 a waveform is generated.

One may use, e.g., a conventional signal generator to produce the desired electromagnetic wave(s) in step 256. As is known to those skilled in the art, a signal generator is an instrument that delivers signals of precise frequency and amplitude, usually over a wide range. Reference may be had, e.g., to United States patents 6,256,157 (method for removing noise spikes), reissue 35,574 (method for acoustical echo cancellation), 5,126,681 (in-wire selective active cancellation system), 4,612,549 (interference canceller loop having automatic nulling of the loop phase shift for use in a reception system), 5,054,118 (balanced mixer using filters), 5,046,010 (fixed-echo canceling radio altimeter), 3,604,947(variable filter device), 5,950,119 (image-reject mixers), 4,520,475 (duplex communication transceiver with modulation cancellation), 5,131,032 (echo canceller), 6,169,912 (RF front end with signal cancellation), 6,114,983 (electronic counter measures in radar), 5,023,620 (cross-polarization interference cancellation system), 5,924,024, 4,992,798 (interference canceller), 6,211,671 (interference-cancellation system for electromagnetic receivers), 6,208,135 (inductive noise cancellation for electromagnetic pickups), 6,269,165 (apparatus for reduction of

unwanted feedback), 5,768,699 (amplifier with detuned test signal cancellation), 4,575,862 (cross-polarization distortion canceller), 6,147,576 (filter designs using parasitic and field effects), 4,438,530 (adaptive cross-polarization interference cancellation system), and the like. The entire disclosure of each of these United States patents is hereby incorporated by reference into this specification.

Referring again to Figure 9, in step 256 one or more electromagnetic waves will be generated so that, when such wave(s) is mixed with the high-frequency electromagnetic waves produced by antennas 258, 260, and 262 in a mixer and mixed in step 258, some or all of such high-frequency electromagnetic waves will be cancelled.

Thus, as will be apparent, the process of Figure 9 converts some of the high-frequency electromagnetic energy produced during MRI analyses to energy used for thermoelectric cooling (step 252), for conversion from alternating current to direct current (in step 246), for producing cancellable waveforms, and for mixing. All of this energy is energy that is not used to produce undesired heating of cardiac tissue.

#### A preferred sputtering process

On December 29, 2003, applicants filed United States patent application 10/747,472, for "Nanoelectrical Compositions." The entire disclosure of this United States patent application is hereby incorporated by reference into this specification.

U.S.S.N. 10/747,472, at pages 10-15 thereof (and by reference to its Figure 9), described the "preparation of a doped aluminum nitride assembly." This portion of U.S.S.N. 10/747,472 is specifically incorporated by reference into this specification. It is also described below, by reference to Figure 10, which is similar to the Figure 9 of U.S.S.N. 10/747,472 but utilizes different reference numerals.

The system depicted in Figure 10 may be used to prepare an assembly comprised of moieties A, B, and C (see Figure 3). Figure 10 will be described hereinafter with reference to one of the preferred ABC moieties, i.e., aluminum nitride doped with magnesium.

Figure 10 is a schematic of a deposition system 300 comprised of a power supply 302 operatively connected via line 304 to a magnetron 306. Disposed on top of magnetron 306 is a target 308. The target 308 is contacted by gas 310 and gas 312, which cause sputtering of the target 308. The material so sputtered contacts substrate 314 when allowed to do so by the absence of shutter 316.

In one preferred embodiment, the target 308 is mixture of aluminum and magnesium atoms in a molar ratio of from about 0.05 to about 0.5 Mg/(Al + Mg). In one aspect of this embodiment, the ratio of Mg/(Al + Mg) is from about 0.08 to about 0.12. These targets are commercially available and are custom made by companies such as, e.g., Kurt Lasker and Company of Pittsburgh, Pa.

The power supply 302 preferably provides pulsed direct current. Generally, power supply 302 provides power in excess of 300 watts, preferably in excess of 500 watts, and more preferably in excess of 1,000 watts. In one embodiment, the power supplied by power supply 302 is from about 1800 to about 2500 watts.

The power supply preferably provides rectangular-shaped pulses with a duration (pulse width) of from about 10 nanoseconds to about 100 nanoseconds. In one embodiment, the pulse width is from about 20 to about 40 nanoseconds.

In between adjacent pulses, preferably substantially no power is delivered. The time between adjacent pulses is generally from about 1 microsecond to about 10

microseconds and is generally at least 100 times greater than the pulse width. In one embodiment, the repetition rate of the rectangular pulses is preferably about 150 kilohertz.

One may use a conventional pulsed direct current (d.c.) power supply. Thus, e.g., one may purchase such a power supply from Advanced Energy Company of Colorado, and/or from ENI Company of Rochester, New York.

The pulsed d.c. power from power supply 302 is delivered to a magnetron 306, that creates an electromagnetic field near target 308. In one embodiment, a magnetic field has a magnetic flux density of from about 0.01 Tesla to about 0.1 Tesla.

As will be apparent, because the energy provided to magnetron 306 comprises intermittent pulses, the resulting magnetic fields produced by magnetron 306 will also be intermittent. Without wishing to be bound to any particular theory, applicants believe that the use of such intermittent electromagnetic energy yields better results than those produced by continuous radio-frequency energy.

Referring again to Figure 10, it will be seen that the process depicted preferably is conducted within a vacuum chamber 118 in which the base pressure is from about  $1 \times 10^{-8}$  Torr to about 0.000005 Torr. In one embodiment, the base pressure is from about 0.000001 to about 0.000003 Torr.

The temperature in the vacuum chamber 318 generally is ambient temperature prior to the time sputtering occurs.

In one aspect of the embodiment illustrated in Figure 10, argon gas is fed via line 310, and nitrogen gas is fed via line 312 so that both impact target 308, preferably in an ionized state.

The argon gas, and the nitrogen gas, are fed at flow rates such that the flow rate of the argon gas divided by the flow rate of the nitrogen gas preferably is from about 0.6 to about 1.2. In one aspect of this embodiment, such ratio of argon to nitrogen is from about 0.8 to about 0.95. Thus, for example, the flow rate of the argon may be 20 standard cubic centimeters per minute, and the flow rate of the nitrogen may be 23 standard cubic feet per minute.

The argon gas, and the nitrogen gas, contact a target 308 that is preferably immersed in an electromagnetic field. This field tends to ionize the argon and the nitrogen, providing ionized species of both gases. It is such ionized species that bombard target 308.

In one embodiment, target 308 may be, e.g., pure aluminum. In one preferred embodiment, however, target 308 is aluminum doped with minor amounts of one or more of the aforementioned moieties B.

In the latter embodiment, the moieties B are preferably present in a concentration of from about 1 to about 40 molar percent, by total moles of aluminum and moieties B. It is preferred to use from about 5 to about 30 molar percent of such moieties B.

The ionized argon gas, and the ionized nitrogen gas, after impacting the target 308, creates a multiplicity of sputtered particles 320. In the embodiment illustrated in Figure 10, the shutter 316 prevents the sputtered particles 320 from contacting substrate 314.

When the shutter 316 is removed, however, the sputtered particles 320 can contact and coat the substrate 314.

In one embodiment, illustrated in Figure 10, the temperature of substrate 314 is controlled by controller 322, that can heat the substrate (by means such as a conduction heater or an infrared heater) and/or cool the substrate (by means such as liquid nitrogen or water).

The sputtering operation increases the pressure within the region of the sputtered particles 320. In general, the pressure within the area of the sputtered particles 320 is at least 100 times, and preferably 1000 times, greater than the base pressure.

Referring again to Figure 10, a cryo pump 324 is preferably used to maintain the base pressure within vacuum chamber 318. In the embodiment depicted, a mechanical pump (dry pump) 326 is operatively connected to the cryo pump 324. Atmosphere from chamber 318 is removed by dry pump 326 at the beginning of the evacuation. At some point, shutter 328 is removed and allows cryo pump 324 to continue the evacuation. A valve 330 controls the flow of atmosphere to dry pump 326 so that it is only open at the beginning of the evacuation.

It is preferred to utilize a substantially constant pumping speed for cryo pump 324, i.e., to maintain a constant outflow of gases through the cryo pump 324. This may be accomplished by sensing the gas outflow via sensor 332 and, as appropriate, varying the extent to which the shutter 328 is open or partially closed.

Without wishing to be bound to any particular theory, applicants believe that the use of a substantially constant gas outflow rate insures a substantially constant deposition of sputtered nitrides.

Referring again to Figure 10, and in one embodiment thereof, it is preferred to clean the substrate 314 prior to the time it is utilized in the process. Thus, e.g., one may

use detergent to clean any grease or oil or fingerprints off the surface of the substrate.

Thereafter, one may use an organic solvent such as acetone, isopropyl alcohol, toluene, etc.

In one embodiment, the cleaned substrate 314 is presputtered by suppressing sputtering of the target 308 and sputtering the surface of the substrate 314.

As will be apparent to those skilled in the art, the process depicted in Figure 10 may be used to prepare coated substrates 314 comprised of moieties other than doped aluminum nitride.

#### A preferred coated substrate

Figure 11 is a schematic, partial sectional illustration of a coated substrate 400 that, in the preferred embodiment illustrated, is comprised of a coating 402 disposed upon a stent 404. As will be apparent, only one side of the coated stent 404 is depicted for simplicity of illustration.

In the preferred coated substrate depicted in Figure 11, the coating 402 may be comprised of one layer of material, two layers of material, or three or more layers of material. In the embodiment depicted in Figure 11, two coating layers, layers 406 and 408, are used.

Regardless of the number of coating layers used, it is preferred that the total thickness 410 of the coating 402 be at least about 400 nanometers and, preferably, be from about 400 to about 4,000 nanometers. In one embodiment, thickness 410 is from about 600 to about 1,000 nanometers. In another embodiment, thickness 410 is from about 750 to about 850 nanometers.

The substrate 404 has a thickness 412 that is substantially greater than the thickness 410. As will be apparent, the coated substrate 400 is not drawn to scale.

In general, the thickness 410 is less than about 5 percent of thickness 412 and, more preferably, less than about 2 percent. In one embodiment, the thickness of 410 is no greater than about 1.5 percent of the thickness 412.

The substrate 404, prior to the time it is coated with coating 402, has a certain flexural strength, and a certain spring constant.

The flexural strength is the strength of a material in bending, i.e., its resistance to fracture. As is disclosed in ASTM C-790, the flexural strength is a property of a solid material that indicates its ability to withstand a flexural or transverse load.

As is known to those skilled in the art, the spring constant is the constant of proportionality  $k$  which appears in Hooke's law for springs. Hooke's law states that:  $F = -kx$ , wherein  $F$  is the applied force and  $x$  is the displacement from equilibrium. The spring constant has units of force per unit length.

Means for measuring the spring constant of a material are well known to those skilled in the art. Reference may be had, e.g., to United States patents 6,360,589 (device and method for testing vehicle shock absorbers), 4,970,645 (suspension control method and apparatus for vehicle), 6,575,020, 4,157,060, 3,803,887, 4,429,574, 6,021,579, and the like. The entire disclosure of each of these United States patents is hereby incorporated by reference into this specification.

Referring again to Figure 11, the flexural strength of the uncoated substrate 404 differs from the flexural strength of the coated substrate 404 by no greater than about 5

percent. Similarly, the spring constant of the uncoated substrate 404 differs from the spring constant of the coated substrate 404 by no greater than about 5 percent.

Referring again to Figure 11, and in the preferred embodiment depicted, the substrate 404 is comprised of a multiplicity of openings through which biological material is often free to pass. As will be apparent to those skilled in the art, when the substrate 404 is a stent, it will be realized that the stent has a mesh structure.

Figure 12 is a schematic view of a typical stent 500 that is comprised of wire mesh 502 constructed in such a manner as to define a multiplicity of openings 504. The mesh material is typically a metal or metal alloy, such as, e.g., stainless steel, Nitinol (an alloy of nickel and titanium), niobium, copper, etc.

Typically the materials used in stents tend to cause current flow when exposed to a field 506. When the field 506 is a nuclear magnetic resonance field, it generally has a direct current component, and a radio-frequency component. For MRI (magnetic resonance imaging) purposes, a gradient component is added for spatial resolution.

The material or materials used to make the stent itself has certain magnetic properties such as, e.g., magnetic susceptibility. Thus, e.g., niobium has a magnetic susceptibility of  $1.95 \times 10^{-6}$  centimeter-gram-second units. Nitonol has a magnetic susceptibility of from about 2.5 to about  $3.8 \times 10^{-6}$  centimeter-gram-second units. Copper has a magnetic susceptibility of from -5.46 to about  $-6.16 \times 10^{-6}$  centimeter-gram-second units.

When any particular material is used to make the stent, its response to an applied MRI field will vary depending upon, e.g., the relative orientation of the stent in relationship to the fields (including the d.c. field, the r.f. field, an the gradient field).

Any particular stent implanted in a human body will tend to have a different orientation than any other stent implanted in another human body due, in part, to the uniqueness of each human body. Thus, it cannot be predicated a priori what how any particular stent will respond to a particular MRI field.

The solution provided by applicants' invention tends to cancel, or compensate for, the response of any particular stent in any particular body when exposed to an MRI field.

Referring again to Figure 12, and to the uncoated stent 500 depicted therein, when an MRI field 506 is imposed upon the stent, it will tend to induce eddy currents. As used in this specification, the term eddy currents refers to loop currents and surface eddy currents.

Referring to Figure 12, the MRI field 506 will induce a loop current 508. As is apparent to those skilled in the art, the MRI field 506 is an alternating current field that, as it alternates, induces an alternating eddy current 508. The radio-frequency field is also an alternating current field, as is the gradient field. By way of illustration, when the d.c. field is about 1.5 Tesla, the r.f. field has frequency of about 64 megahertz. With these conditions, the gradient field is in the kilohertz range, typically having a frequency of from about 2 to about 200 kilohertz.

Applying the well-known right hand rule, the loop current 508 will produce a magnetic field 510 extending into the plane of the paper and designated by an "x." This magnetic field 510 will tend to oppose the direction of the applied field 506.

Referring again to Figure 12, when the stent 500 is exposed to the MRI field 506, a surface eddy current will be produced where there is a relatively large surface area of conductive material such as, e.g., at junction 514.

The stent 500 must be constructed to have certain desirable mechanical properties. However, the materials that will provide the desired mechanical properties generally do not have desirable magnetic and/or electromagnetic properties. In an ideal situation, the stent 500 will produce no loop currents<sup>508</sup> and no surface eddy currents<sup>512</sup>; in such situation, the stent 500 would have an effective zero magnetic susceptibility.

The prior art has heretofore been unable to provide such an ideal stent. Applicants' invention allows one to compensate for the deficiencies of the current stents by canceling the undesirable effects due to their magnetic susceptibilities, and/or by compensating for such undesirable effects.

Figure 13 is a graph of the magnetization of an object (such as an uncoated stent, or a coated stent) when subjected to an electromagnetic field, such as an MRI field. It will be seen that, at different field strengths, different materials have different magnetic responses.

Thus, e.g., it will be seen that copper, at a d.c. field strength of 1.5 Tesla, is changing its magnetization as a function of the composite field strength (including the d.c. field strength, the r.f. field strength, and the gradient field strength) at a rate (defined by delta-magnetization/delta composite field strength) that is decreasing. With regard to the r.f. field and the gradient field, it should be understood that the order of magnitude of these fields is relatively small compared to the d.c. field, which is usually about 1.5 Tesla.

Referring again to Figure 13, it will be seen that the slope of line 602 is negative. This negative slope indicates that copper, in response to the applied fields, is opposing the applied fields. Because the applied fields (including r.f. fields, and the gradient fields), are required for effective MRI imaging, the response of the copper to the applied

fields tends to block the desired imaging, especially with the loop current and the surface eddy current described hereinabove.

Referring again to Figure 13, the ideal magnetization response is illustrated by line 604, which is the response of the coated substrate of this invention, and wherein the slope is substantially zero. As used herein, the term substantially zero includes a slope will produce an effective magnetic susceptibility of from about  $1 \times 10^{-7}$  to about  $1 \times 10^{-8}$  centimeters-gram-second (cgs) units..

Referring again to Figure 13, one means of correcting the negative slope of line 602 is by coating the copper with a coating which produces a response 606 with a positive slope so that the composite material produces the desired effective magnetic susceptibility of from about  $1 \times 10^{-7}$  to about  $1 \times 10^{-8}$  centimeters-gram-second (cgs) units.

Figure 11 illustrates a coating that will produce the desired correction for the copper substrate 404. Referring to Figure 11, it will be seen that, in the embodiment depicted, the coating 402 is comprised of at least nanomagnetic material 420 and nanodielectric material 422.

In one embodiment, the nanomagnetic material 402 preferably has an average particle size of less than about 20 nanometers and a saturation magnetization of from 10,000 to about 26,000 Gauss.

In one embodiment, the nanomagnetic material used is iron. In another embodiment, the nanomagnetic material used is FeAlN. In yet another embodiment, the nanomagnetic material is FeAl. Other suitable materials will be apparent to those skilled

in the art and include, e.g., nickel, cobalt, magnetic rare earth materials and alloys, thereof, and the like.

The nanodielectric material 422 preferably has a resistivity at 20 degrees Centigrade of from about  $1 \times 10^{-5}$  ohm-centimeters to about  $1 \times 10^{13}$  ohm-centimeters.

Referring again to Figure 11, the nanomagnetic material 420 is preferably homogeneously dispersed within nanodielectric material 422, which acts as an insulating matrix. In general, the amount of nanodielectric material 422 in coating 402 exceeds the amount of nanomagnetic material 420 in such coating 402. In general, the coating 402 is comprised of at least about 70 mole percent of such nanodielectric material (by total moles of nanomagnetic material and nanodielectric material). In one embodiment, the coating 402 is comprised of less than about 20 mole percent of the nanomagnetic material, by total moles of nanomagnetic material and nanodielectric material. In one embodiment, the nanodielectric material used is aluminum nitride.

Referring again to Figure 11, one may optionally include nanoconductive 424 in the coating 402. This nanoconductive material generally has a resistivity at 20 degrees Centigrade of from about  $1 \times 10^{-6}$  ohm-centimeters to about  $1 \times 10^{-5}$  ohm-centimeters; and it generally has an average particle size of less than about 100 nanometers. In one embodiment, the nanoconductive material used is aluminum.

Referring again to Figure 11, and in the embodiment depicted, it will be seen that two layers 406 and 408 are used to obtain the desired correction. In one embodiment, three or more such layers are used. This embodiment is depicted in Figure 11A.

Figure 11A is a schematic illustration of a coated substrate that is similar to coated substrate 400 but differs therefrom in that it contains two layers of dielectric

material 440 and 442. In one embodiment, only one such layer of dielectric material 440 is issued. Notwithstanding the use of additional layers 440 and 442, the coating 402 still preferably has a thickness 410 of from about 400 to about 4000 nanometers.-

As will be apparent, it may be difficult with only one layer of coating material to obtain the desired correction for the material comprising the stent (see Figure 13). With a multiplicity of layers comprising the coating 402, which may have the same and/or different thicknesses, and/or the same and/or different compositions, more flexibility is provided in obtaining the desired correction.

Figure 13 illustrates the desired correction in terms of magnetization. Figure 14 illustrates the desired correction in terms of reactance.

With regard to reactance, the r.f. field and the gradient field are treated as a radiation source which is applied to a living organism comprised of a stent in contact with biological material. The stent, with or without a coating, reacts to the radiation source by exhibiting a certain inductive reactance and a certain capacitative reactance. The net reactance is the difference between the inductive reactance and the capacitative reactance; and it is desired that the net reactance be as close to zero as is possible. When the net reactance is greater than zero, it distorts some of the applied MRI fields and thus interferes with their imaging capabilities. Similarly, when the net reactance is less than zero, it also distorts some of the applied MRI fields.

#### Nullification of the susceptibility contribution due to the substrate

As will be apparent by reference, e.g., to Figure 13, the copper substrate depicted therein has a negative susceptibility, the coating depicted therein has a positive susceptibility, and the coated substrate thus has a substantially zero susceptibility. As will

also be apparent, some substrates (such niobium, nitinol, stainless steel, etc.) have positive susceptibilities. In such cases, and in one preferred embodiment, the coatings should preferably be chosen to have a negative susceptibility so that, under the conditions of the MRI radiation (or of any other radiation source used), the net susceptibility of the coated object is still substantially zero.

The magnetic susceptibilities of various substrate materials are well known. Reference may be had, e.g., to pages E-118 to E-123 of the "Handbook of Chemistry and Physics," 63rd edition (CRC Press, Inc., Boca Raton, Florida, 1974).

Once the susceptibility of the substrate material is determined, one can use the following equation:  $\chi_{\text{sub}} + \chi_{\text{coat}} = 0$ , wherein  $\chi_{\text{sub}}$  is the susceptibility of the substrate , and  $\chi_{\text{coat}}$  is the susceptibility of the coating, when each of these is present in a 1/1 ratio. As will be apparent, the aforementioned equation is used when the coating and substrate are present in a 1/1 ratio. When other ratios are used other than a 1/1 ratio, the volume percent of each component must be taken into consideration in accordance with the equation: (volume percent of substrate x susceptibility of the substrate) + (volume percent of coating x susceptibility of the coating) = 0. One may use a comparable formula in which the weight percent of each component is substituted for the volume percent, if the susceptibility is measured in terms of the weight percent.

By way of illustration, and in one embodiment, the uncoated substrate may either comprise or consist essentially of niobium, which has a susceptibility of  $+ 195.0 \times 10^{-6}$  centimeter-gram seconds at 298 degrees Kelvin.

In another embodiment, the substrate may contain at least 98 molar percent of niobium and less than 2 molar percent of zirconium. Zirconium has a susceptibility of - -

$-122 \times 0 \times 10^{-6}$  centimeter-gram seconds at 293 degrees Kelvin. As will be apparent, because of the predominance of niobium, the net susceptibility of the uncoated substrate will be positive.

The substrate may comprise Nitinol. Nitinol is a paramagnetic alloy, an intermetallic compound of nickel and titanium; the alloy preferably contains from 50 to 60 percent of nickel, and it has an permeability value of about 1.002. The susceptibility of Nitinol is positive.

Nitinols with nickel content ranging from about 53 to 57 percent are known as "memory alloys" because of their ability to "remember" or return to a previous shape upon being heated.. which is an alloy of nickel and titanium, in an approximate 1/1 ratio. The susceptibility of Nitinol is positive.

The substrate may comprise tantalum and/or titanium, each of which has a positive susceptibility. See, e.g., the CRC handbook cited above.

When the uncoated substrate has a positive susceptibility, the coating to be used for such a substrate should have a negative susceptibility. Referring again to said CRC handbook, it will be seen that the values of negative susceptibilities for various elements are -9.0 for beryllium, -280.1 for bismuth (s), -10.5 for bismuth (l), - 6.7 for boron, - 56.4 for bromine (l), -73.5 for bromine(g), -19.8 for cadmium(s), -18.0 for cadmium(l), -5.9 for carbon(dia), -6.0 for carbon (graph), -5.46 for copper(s), -6.16 for copper(l), -76.84 for germanium, -28.0 for gold(s), -34.0 for gold(l), -25.5 for indium, -88.7 for iodine(s), -23.0 for lead(s), -15.5 for lead(l), -19.5 for silver(s), -24.0 for silver(l), -15.5 for sulfur(alpha), -14.9 for sulfur(beta), -15.4 for sulfur(l), -39.5 for tellurium(s), -6.4 for tellurium(l), -37.0 for tin(gray), -31.7 for tin(gray), -4.5 for tin(l), -11.4 for zinc(s),

-7.8 for zinc(l), and the like. As will be apparent, each of these values is expressed in units equal to the number in question  $\times 10^{-6}$  centimeter-gram seconds at a temperature at or about 293 degrees Kelvin. As will also be apparent, those materials which have a negative susceptibility value are often referred to as being diamagnetic.

By way of further reference, a listing of organic compounds that are diamagnetic is presented on pages E123 to E134 of the aforementioned "Handbook of Chemistry and Physics," 63rd edition (CRC Press, Inc., Boca Raton, Florida, 1974).

Preferred magnetic materials that may be used in the process of the invention

In one embodiment, and referring again to the aforementioned "Handbook of Chemistry and Physics," 63rd edition (CRC Press, Inc., Boca Raton, Florida, 1974), one or more of the following magnetic materials described below are preferably incorporated into the coating.

The desired magnetic materials in this embodiment preferably have a positive susceptibility, with values ranging from  $+1 \times 10^{-6}$  centimeter-gram seconds at a temperature at or about 293 degrees Kelvin, to about  $1 \times 10^6$  centimeter-gram seconds at a temperature at or about 293 degrees Kelvin.

Thus, by way of illustration and not limitation, one may use materials such as Alnicol (see page E-112 of the CRC handbook), which is an alloy containing nickel, aluminum, and other elements such as, e.g., cobalt and/or iron. Thus, e.g., one may use silicon iron (see page E113 of the CRC handbook), which is an acid resistant iron containing a high percentage of silicon. Thus, e.g., one may use steel (see page 117 of the CRC handbook). Thus, e.g., one may use elements such as dysprosium, erbium, europium, gadolinium, hafnium, holmium, manganese, molybdenum, neodymium,

nickel-cobalt, alloys of the above, and compounds of the above such as, e.g., their oxides, nitrides, carbonates, and the like.

Referring to Figure 14, and to the embodiment depicted therein, it will be seen that the uncoated stent has an effective inductive reactance at a d.c. field of 1.5 Tesla that exceeds its capacitative reactance, whereas the coating 704 has a capacitative reactance that exceeds its inductive reactance. The coated (composite) stent 706 has a net reactance that is substantially zero.

As will be apparent, the effective inductive reactance of the uncoated stent 702 may be due to a multiplicity of factors including, e.g., the positive magnetic susceptibility of the materials which it is comprised of it, the loop currents produced, the surface eddy produced, etc. Regardless of the source(s) of its effective inductive reactance, it can be "corrected" by the use of one or more coatings which provide, in combination, an effective capacitative reactance that is equal to the effective inductive reactance.

Referring again to Figure 11, and in the embodiment depicted, plaque particles 430,432 are disposed on the inside of substrate 404. When the net reactance of the coated substrate 404 is essentially zero, the imaging field 440 can pass substantially unimpeded through the coating 402 and the substrate 404 and interact with the plaque particles 430/432 to produce imaging signals 441.

The imaging signals 441 are able to pass back through the substrate 404 and the coating 402 because the net reactance is substantially zero. Thus, these imaging signals are able to be received and processed by the MRI apparatus.

Thus, by the use of applicant's technology, one may negate the negative substrate effect and, additionally, provide pathways for the image signals to interact with the

desired object to be imaged (such as, e.g., the plaque particles) and to produce imaging signals that are capable of escaping the substrate assembly and being received by the MRI apparatus.

Incorporation by reference of certain pending patent applications

In accordance with the Manual of Patent Examining Procedure (M.P.E.P.), section 60.8.01(p), applicants are hereby incorporating by reference certain disclosure from their copending patent applications into the instant case. In particular, applicants are incorporating the following disclosures into this case: (1) U.S.S.N. 60/533,200, Coated stent assembly, filed on December 30, 2003, (2) U.S.S.N. 10/747,472, "Nanoelectrcial Compositions," filed on December 29, 2003, (3) U.S.S.N. 10/744,543, "Optical Fiber Assembly," filed on December 22, 2003, (4) U.S.S.N. 60/525,916, "MRI Contrast Agent Assembly," filed on December 1, 2003, (5) U.S.S.N. 10/477,120, "Novel Coating Process," filed on June 9, 2003, (6) U.S.S.N. 10/409,505, "Nanomagnetic Composition," filed on April 8, 2003, (7) U.S.S.N. 10/384,288, "Magnetic Resonance Imaging Coated Assembly," filed on March 7, 2003, (8) U.S.S.N. 10/373,377, "Protective Assembly," filed on February 24, 2003, (9) U.S.S.N. 10/366,082, "Magnetically Shielded Assembly," filed on February 12, 2003, (10) U.S.S.N. 10/336,088, "Optical Fiber Assembly," filed on January 3, 2003, (11) U.S.S.N. 10/324,773, "Nanomagnetically Shielded Substrate," filed on December 18, 2002, (12) U.S.S.N. 10/303,264, "Magnetically Shielded Assembly," filed on November 25, 2002, (13) U.S.S.N. 10/273,738, "Nanomagnetically Shielding Assembly," filed on October 18, 2002, (14) U.S.S.N. 10/260,247, "Magnetically Shielded Assembly," filed on September 30, 2002, (15) U.S.S.N. 10/242,969, "Magnetically Shielded Conductor," filed on September 13,

2002, (16) U.S.S.N. 10/090,553, "Mangetically Shielded Conductor," filed on March 4, 2002, and (17) U.S.S.N. 10/054,407, "Magnetically Shielded Conductor," filed on January 22, 2002. The entire disclosure of each of these United States patent applications is hereby incorporated by reference into this patent application.

Preparation of a coated stent

In one embodiment, the stent described elsewhere in this specification is coated with a coating that provides specified "signature" when subjected to the MRI field, regardless of the orientation of the stent. This effect is illustrated in Figure 15.

Figure 15 is a plot of the image response of the MRI apparatus (image clarity) as a function of the applied MRI fields. The image clarity is generally related to the net reactance.

Referring to Figure 15 plot 802 illustrates the response of a particular uncoated stent in a first orientation in a patient's body. As will be seen from plot 802, this stent in this first orientation has an effective net inductive response.

Figure 15, and in particular plot 804, illustrates the response of the same uncoated stent in a second orientation in a patient's body. As has been discussed elsewhere in this specification, the response of an uncoated stent is orientation specific. Thus, plot 804 shows a smaller inductive response than plot 802.

When the uncoated stent is coated with the appropriate coating, as described elsewhere in this specification, the net reactive effect is zero, as is illustrated in plot 806. In this plot 806, the magnetic response of the substrate is nullified regardless of the orientation of such substrate within a patient's body.

In one embodiment, illustrated as plot 808, a stent is coated in such a manner that its net reactance is substantially larger than zero, to provide a unique imaging signature for such stent. Because the imaging response of such coated stent is also orientation independent, one may determine its precise location in a human body with the use of conventional MRI imaging techniques. In effect, the coating on the stent 808 acts like a tracer, enabling one to locate the position of the stent 808 at will.

In one embodiment, if one knows the MRI signature of a stent in a certain condition, one may be able to determine changes in such stent. Thus, for example, if one knows the signature of such stent with plaque deposited on it, and the signature of such stent without plaque deposited on it, one may be able to determine a human body's response to such stent.

#### Devices incorporating the shielded conductor assembly

In this section of the specification, various devices that incorporate the shielded conductor assemblies disclosed in, e.g., Figures 6A through 6E are described. The devices described in this section of the specification may also utilize other coating constructs disclosed in this specification.

The inventions described in this section of the specification relates generally to an implantable device that is immune or hardened to electromagnetic insult or interference. More particularly, and in one preferred embodiment, the invention is directed to implantable medical leads that utilize shielding to harden or make these systems immune from electromagnetic insult, namely magnetic-resonance imaging insult.

Reference may be had to an article by Neil Mathur et al. entitled "Mesoscopic Texture in Magnanites" (January, 2003, Physics Today" for a discussion of the fact that

"...in certain oxides of manganese, a spectacularly diverse range of exotic electronic and magnetic phases can coexist at different locations within a single crystal. This striking behavior arises in Figure 12, which is a schematic sectional view of substrate 901, which is part of an implantable medical device (not shown). Referring to Figure 16, and to the embodiment depicted therein, it will be seen that substrate 901 is coated with nanomagnetic particulate material 902.

In the embodiment depicted in Figure 16, the substrate 901 may be a cylinder, such as an enclosure for a catheter, medical stent, guide wire, and the like. The assembly depicted in Figure 16 preferably includes a channel 508 located on the periphery of the medical device. An actively circulating, heat-dissipating fluid (not shown) can be pumped into channel 908 through port 907, and exit channel 908 through port 909. The heat-dissipation fluid (not shown) will draw heat to another region of the device, including regions located outside of the body where the heat can be dissipated at a faster rate. In the embodiment depicted, the heat-dissipating flow flows internally to the layer of nanomagnetic particles 902

In another embodiment, not shown, the heat dissipating fluid flows externally to the layer of nanomagnetic particulate material 902.

In another embodiment (not shown), one or more additional polymer layers (not shown) are coated on top of the layer of nanomagnetic particulate 902. In one aspect of this embodiment, a high thermal conductivity polymer layer is coated immediately over the layer of nanomagnetic particulate 902; and a low thermal conductivity polymer layer is coated over the high thermal conductivity polymer layer. It is preferred that neither the high thermal conductivity polymer layer nor the low thermal conductivity

polymer layer be electrically or magnetically conductive. In the event of the occurrence of "hot spots" on the surface of the medical device, heat from the localized "hot spots" will be conducted along the entire length of the device before moving radially outward through the insulating outer layer. Thus, heat is distributed more uniformly.

Figures 17A, 17B, and 17C are schematic views of a catheter assembly similar to the assembly depicted in Figure 2 of United States patent 3,995,623; the entire disclosure of such patent is hereby incorporated by reference into this specification. Referring to Figure 6 of such patent, and also to Figures 17A, 17B, and 17C, it will be seen that catheter tube 625 contains multiple lumens 927, 929, 931, and 933, which can be used for various functions such as inflating balloons, enabling electrical conductors to communicate with the distal end of the catheter, etc. While such four lumens are shown, it is to be understood that this invention applies to a catheter with any number of lumens.

The similar catheter disclosed and claimed in United States patent 3,995,623 may be shielded by coating it in whole or in part with a coating of nanomagnetic particulate.

In the embodiment depicted in Figure 17B, a nanomagnetic material 935 is applied to the interior walls of multiple lumens 927, 929, 931, 933 within a single catheter 934 or the common exterior wall 939 or imbibed into the common wall 939.

In the embodiment depicted in Figure 17C, a nanomagnetic material 925 is applied to the mesh-like material 941 used within the wall of catheter 936 to give it desired mechanical, electrical, and magnetic properties..

In another embodiment (not shown) a sheath coated with nanomagnetic material on its internal surface, exterior surface, or imbibed into the wall of such sheath,

is placed over a catheter to shield it from electromagnetic interference. In this manner, existing catheters can be made MRI safe and compatible. The modified catheter assembly thus produced is resistant to electromagnetic radiation.

Figures 18A through 18G are schematic views of a catheter assembly 1000 consisting of multiple concentric elements. While two elements are shown; 1020 and 1022 are shown, it is to be understood that any number of overlapping elements may be used, either concentrically or planarly positioned with respect to each other.

Referring to Figures 18A through 18G, and in the preferred embodiment depicted therein, it will be seen that catheter assembly 1000 comprises an elongated tubular construction having a single, central or axial lumen 1010. The exterior catheter body 1022 and concentrically positioned internal catheter body 1020 with internal lumen 1012 are preferably flexible, i.e., bendable, but substantially non-compressible along its length. The catheter bodies 1020 and 1022 may be made of any suitable material. A presently preferred construction comprises an outer wall 1022 and inner wall 1020 made of a polyurethane, silicone, or nylon.

The outer wall 1022 preferably comprises an imbedded braided mesh of stainless steel or the like to increase torsional stiffness of the catheter assembly 1000 so that, when a control handle, not shown, is rotated, the tip sectionally of the catheter will rotate in corresponding manner.

The catheter assembly 1000 may be shielded by coating it in whole or in part with a coating of nanomagnetic particulate 935, in any one or more of the following manners.

Referring to figure 18A, a nanomagnetic material 935 may be coated on the outside surface of the inner concentrically positioned catheter body 1020.

Referring to figure 18C, a nanomagnetic material 935 may be imbibed into the walls of the inner concentrically positioned catheter body 1020 and externally positioned catheter body 1022. Although not shown, a nanomagnetic material may be imbibed solely into either inner concentrically positioned catheter body 1020 or externally positioned catheter body 1022.

Referring to Figure 18D, a nanomagnetic material 935 may be coated onto the exterior wall of the inner concentrically positioned catheter body 1020 and external catheter body 1022.

Referring to Figure 18E, a nanomagnetic material 935 may be coated onto the interior wall of the inner concentrically positioned catheter body 1020 and externally wall of externally positioned catheter body 1022.

Referring to Figure 18F, a nanomagnetic material 935 may be coated on the outside surface of the externally positioned catheter body 1022.

Referring to Figure 18G, a nanomagnetic material 935 may be coated onto the exterior surface of an internally positioned solid element 1027.

By way of fuirther illustration, one may apply nanomagnetic particulate material to one or more of the catheter assemblies disclosed and claimed in United States patents 5,178,803, 5,041,083, 6,283,959, 6,270,477, 6,258,080, 6,248,092, 6,238,408, 6,208,881, 6,190,379, 6,171,295, 6,117,064, 6,019,736, 5,964,757, 5,853,394, and 6,235,024, the entire disclosure of each of which is hereby incorporated by reference into this specification. The catheters assemblies disclosed and claimed in the

above-mentioned United States patents may be shielded by coating them in whole or in part with a coating of nanomagnetic particulate 935

Figures 19A, 19B. and 19C are schematic views of a guide wire assembly 1100 for insertion into vascular vessel (not shown), and it is similar to the assembly depicted in United States patent 5,460,187, the entire disclosure of such patent is incorporated by reference into this specification. Referring to Figure 19A, a coiled guide wire 1110 is formed of a proximal section (not shown) and central support wire 120 which terminates in hemispherical shaped tip 115. The proximal end has a retaining device (not shown) that enables the person operating the guide wire to turn and orient the guide wire within the vascular conduit.

The guide wire assembly may be shielded by coating it in whole or in part with a coating of nanomagnetic particulate 935.

By way of further illustration, one may coat with nanomagnetic particulate matter the guide wire assemblies disclosed and claimed in United States patents: 5,211,183, 6,168,604, 6,093,157, 6,019,737, 6,001,068, 5,938,623, 5,797,857, 5,588,443, 5,452,726, and the like; the entire disclosure of each of these United States patents is hereby incorporated by reference into this specification.

Figures 20A and 20B are schematic views of a medical stent assembly 1200 similar to the assembly depicted in Figure 15 of United States patent 5,443,496; the entire disclosure of such patent is hereby incorporated by reference into this specification.

Referring to Figure 20, a self-expanding stent 1200 comprising joined metal stent elements 1262 is shown. The stent 1200 also comprises a flexible film 1264. The flexible film 1264 can be applied as a sheath to the metal stent elements 1262 after which the

stent 1200 can be compressed, attached to a catheter, and delivered through a body lumen to a desired location. Once in the desired location, the stent 1200 can be released from the catheter and expanded into contact with the body lumen, where it can conform to the curvature of the body lumen. The flexible film 1264 is able to form folds, which allow the stent elements to readily adapt to the curvature of the body lumen. The medical stent assembly disclosed and claimed in United States patent 5,443,496 may be shielded by coating it in whole or in part with a nanomagnetic coating 935 (not shown).

In the embodiment depicted in Figure 20A, flexible film 1264 is coated with a nanomagnetic coating 935 on its inside or outside surfaces, or within the film itself.

It is to be understood that any one of the above embodiments may be used independently or in conjunction with one another within a single device.

In yet another embodiment (not shown), a sheath (not shown), coated or imbibed with a nanomagnetic material 935 is placed over the stent 1200, particularly the flexible film 1264, to shield it from electromagnetic interference. In this manner, existing stents can be made MRI safe and i le.

By way of further illustration, one may coat one or more of the medical stent assemblies disclosed and claimed in United States patents: 6,315,794, 6,190,404, 5,968,091, 4,969,458, 6,342,068, 6,312,460, 6,309,412, and 6,305,436, the entire disclosure of each of which is hereby incorporated by reference into this specification. The medical stent assemblies disclosed and claimed in the above-mentioned United States patents may be shielded by coating them in whole or in part with a coating of nanomagnetic particulate, as described above.

Figure 21 is a schematic view of a biopsy probe assembly 1300 similar to the assembly depicted in Figure 1 of United States patent 5,005,585 the entire disclosure of such patent is hereby incorporated by reference into this specification. Such biopsy probe assembly 1300 is composed of three separate components, a hollow tubular cannula or needle 1301, a solid intraluminar rod-like stylus 1302, and a clearing rod or probe (not shown).

The components of the assembly 1300 are preferably formed of an alloy, such as stainless steel, which is corrosion resistant and non-toxic. Cannula 1301 has a proximal end (not shown) and a distal end 1305 that is cut at an acute angle with respect to the longitudinal axis of the cannula and provides an annular cutting edge.

By way of further illustration, biopsy probe assemblies are disclosed and claimed in United States patents: 4,671,292, 5,437,283, 5,494,039, 5,398,690, and 5,335,663, the entire disclosure of each of which is hereby incorporated by reference into this specification. The biopsy probe assemblies disclosed and claimed in the above-mentioned United States patents may be shielded by coating them in whole or in part with a coating of nanomagnetic particulate. Thus, e.g., cannula 1301 may be coated, intraluminar stylus 1302 may be coated, and/or the clearing rod may be coated.

In one variation on this design (not shown), a biocompatible sheath is placed over the coated cannula 1301 to protect the nanomagnetic coating from abrasion and from contacting body fluids.

In another embodiment, the biocompatible sheath has on its interior surface or within its walls a nanomagnetic coating.

In yet another embodiment (not shown), a sheath coated or imbued with a nanomagnetic material is placed over the biopsy probe, to shield it from electromagnetic interference. MRI is increasingly being used interoperatively to guide the placement of medical devices such as endoscopes which are very good at treating or examining tissues close up, but generally cannot accurately determine where the tissues being examined are located within the body.

Figures 22A and 22B are schematic views of a flexible tube endoscope assembly 1380. Referring to Figure 22A, the endoscope 1382 employs a flexible tube 1384 with a distally positioned objective lens 1386. Flexible tube 1384 is preferably formed in such manner that the outer side of a spiral tube is closely covered with a braided-wire tube (not shown) formed by weaving fine metal wires into a braid. The spiral tube is formed using a precipitation hardening alloy material, for example, beryllium bronze (copper-beryllium alloy).

By way of further illustration, endoscope tube assemblies are disclosed and claimed in United States patents: 4,868,015, 4,646,723, 3,739,770, 4,327,711, and 3,946,727, the entire disclosure of each of which is hereby incorporated by reference into this specification. The endoscope tube assemblies disclosed and claimed in the above-mentioned United States patents may be shielded by coating them in whole or in part with a coating of nanomagnetic particulate, in any of the following manners.

Referring again to Figure 22A; sheath 1380 is a sheath coated with nanomagnetic material 935 on its inside surface and its exterior surface, or imbued into its structure ; and such sheath 1380 is placed over the endoscope 1382, particularly the flexible tube 1384, to shield it from electromagnetic interference.

In yet another embodiment (not shown), flexible tube 1384 is coated with nanomagnetic materials on its internal surface, or imbued with nanomagnetic materials within its wall.

In another embodiment (not shown), the braided-wire element within flexible tube 1384 is coated with a nanomagnetic material.

In this manner, existing endoscopes can be made MRI safe and compatible. The modified endoscope tube assemblies thus produced are resistant to electromagnetic radiation.

Figures 23A is a schematic illustration of a sheath assembly 1400 comprised of a sheath 1402 whose surface 1404 is comprised of a multiplicity of nanomagnetic materials 1406, 1408, and 1410.

The sheath 1402 may be formed from electrically conductive materials that include metals, carbon composites, carbon nanotubes, metal-coated carbon filaments (wherein the metal may be either a ferromagnetic material such as nickel, cobalt, or magnetic or nonmagnetic stainless steel; a paramagnetic material such as titanium, aluminum, magnesium, copper, silver, gold, tin, or zinc; a diamagnetic material such as bismuth, or well known superconductor materials), metal-coated ceramic filaments (wherein the metal may be one of the following metals: nickel, cobalt, magnetic or non-magnetic stainless steel, titanium, aluminum, magnesium, copper, silver, gold, tin, zinc, bismuth, or well known superconductor materials, a composite of metal-coated carbon filaments and a polymer (wherein the polymer may be one of the following: polyether sulfone, silicone, polymide, polyvinylidene fluoride, epoxy, or urethane), a composite of metal-coated ceramic filaments and a polymer (wherein the polymer may be one of the

following: polyether sulfane, silicone, polyimide, polyvinylidene fluoride, epoxy, or urethane), a composite of metal-coated carbon filaments and a ceramic (wherein the ceramic may be one of the following: cement, silicates, phosphates, silicon carbide, silicon nitride, aluminum nitride, or titanium diboride), a composite of metal-coated ceramic filaments and a ceramic (wherein the ceramic may be one of the following: cement, silicates, phosphates, silicon carbide, silicon nitride, aluminum nitride, or titanium diboride), or a composite of metal-coated (carbon or ceramic) filaments (wherein the metal may be one of the following metals: nickel, cobalt, magnetic or nonmagnetic stainless steel, titanium, aluminum, magnesium, copper, silver, gold, tin, zinc, bismuth, or well known superconductor materials), and a polymer/ceramic combination (wherein the polymer may be one of the following: polyether sulfone, silicone, polyimide, polyvinylidene fluoride, or epoxy and the ceramic may be one of the following: cement, silicates, phosphates, silicon carbide, silicon nitride, aluminum nitride, or titanium diboride).

In one preferred embodiment, the sheath 1402 is comprised of at least about 50 volume percent of the nanomagnetic material 935 described elsewhere in this specification.

As is known to those skilled in the art, liquid crystals are anisotropic materials (that are neither crystalline nor liquid) composed of long molecules that, when aligned, are parallel to each other in long crystals. Ferromagnetic liquid crystals are known to those in the art, and they are often referred to as FMLC. Reference may be had, e.g., to United States patents 4,241,521, 6,451,207, 5,161,030, 6375,330, 6,130,220, and the

like. The entire disclosure of each of these United States patents is hereby incorporated by reference into this specification..

Reference also may be had to United States patent 5,825,448, which describes a reflective liquid crystalline diffractive light valve. The figures of this patent illustrate how the orientations of the magnetic liquid crystal particles align in response to an applied magnetic field. The entire disclosure of this United States patent is hereby incorporated by reference into this specification.

Referring again to Figure 23A. and to the embodiment depicted therein, it will be seen that sheath 1402 may be disposed in whole or in part over medical device 1412. In the embodiment depicted, the sheath 1402 is shown as being bigger than the medical device 1412. It will be apparent that such sheath 1402 may be smaller than the medical device 1412, may be the same size as the medical device 1412, may have a different cross-sectional shape than the medical 1412, and the like.

In one preferred embodiment, the sheath 1402 is disposed over the medical device 1412 and caused to adhere closely thereto. One may create this adhesion either by use of adhesive(s) and/or by mechanical shrinkage.

In one embodiment, shrinkage of the sheath 1412 is caused by heat, utilizing well known shrink tube technology. Reference may be had, e.g., to United States patents 6,438,229, 6,245,053, 6,082,760, 6,055,714, 5,903,693. and the like. The entire disclosure of each of these United States patents is hereby incorporated by reference into this specification.

In another embodiment of the invention, the sheath 1402 is a rigid or flexible tube formed from polytetrafluoroethylene that is heat shrunk into resilient engagement with

the implantable medical device. The sheath can also be formed from heat shrinkable polymer materials e.g., low density polyethylene (LDPE), linear low-density polyethylene (LLDPE), ethylene vinyl acrylate (EVA), ethylene methacrylate (EMA), ethylene methacrylate acid (EMAA) and ethyl glycol methacrylic acid (EGMA). The polymer material of the heat shrinkable sheath should have a Vicat softening point less than 50 degrees Centigrade and a melt index less than 25. A particularly suitable polymer material for the sheath of the invention is a copolymer of ethylene and methyl acrylate. In another embodiment of the invention, the sheath 1402 is a collapsible tube that can be extended over the implantable medical device such as by unrolling or stretching.

In yet another embodiment of the invention, the sheath 1402 contains a tearable seam along its axial length, to enable the sheath to be withdrawn and removed from the implantable device without explanting the device or disconnecting the device from any attachments to its proximal end, thereby enabling the electromagnetic shield to be removed after the device is implanted in a patient. This is a preferred feature of the sheath, since it eliminates the need to disconnect any devices connected to the proximal (external) end of the device, which could interrupt the function of the implanted medical device. This feature is particularly critical if the shield is being applied to a life-sustaining device, such as a temporary implantable cardiac pacemaker.

The ability of the sheath 1402 to be easily removed, and therefore easily disposed of, without disposing of the typically much more expensive medical device being shielded, is a preferred feature since it prevents cross-contamination between patients using the same medical device.

In still another embodiment of the invention, an actively circulating, heat-dissipating fluid is pumped into one or more internal channels within the sheath. The heat-dissipation fluid will draw heat to another region of the device, including regions located outside of the body where the heat can be dissipated at a faster rate. The heat-dissipating flow may preferably flow internally to the layer of nanomagnetic particles 935, or external to the layer of nanomagnetic particulate material 935.

Figure 23B illustrates a process 1401 in which heat 1430 is applied to a shrink tube assembly 1403 to produce the final product 1405. For the sake of simplicity of representation, the controller 1407 has been omitted from Figure 23B.

Referring again to Figure 23A, and in the preferred embodiment depicted therein, it will be seen that a controller 1407 is connected by switch 1409 to the sheath 1402. A multiplicity of sensors 1414 and 1416, e.g., can detect the effectiveness of sheath 1402 by measuring, e.g., the temperature and/or the electromagnetic field strength within the shield 1412. One or more other sensors 1418 are adapted to measure the properties of sheath 1412 at its exterior surface 1404.

For the particular sheath embodiment utilizing a liquid crystal nanomagnetic particle construction, and depending upon the data received by controller 1407, the controller 1407 may change the shielding properties of shield 1412 by delivering electrical and/or magnetic energy to locations 1420, 1422, 1424, etc. The choice of the energy to be delivered, and its location and duration, will vary depending upon the status of the sheath 1412.

In the embodiment depicted in Figure 23A, the medical device may be moved in the direction of arrow 1426, while the sheath 1402 may be moved in the direction of

arrow 1428, to produce the assembly 1401 depicted in Figure 23B. Thereafter, heat may be applied to this assembly to produce the assembly 1405 depicted in Figure 23B.

In one embodiment, not shown, the sheath 1402 is comprised of an elongated element consisting of a proximal end and a distal end, containing one or more internal hollow lumens, whereby the lumens at said distal end may be open or closed; this device is used to temporarily or permanently encase an implantable medical device.

In this embodiment, the elongated hollow element is similar to the sheath disclosed and claimed in United States patent 5,964,730; the entire disclosure of which is hereby incorporated by reference into this specification.

Referring again to Figure 23A, and in the embodiment depicted therein, the sheath 1402 is preferably coated and/or impregnated with nanomagnetic shielding material 1406/1408/1410 that comprises at least 50 percent of its external surface, and/or comprises at least 50 percent of one or more lumen internal surfaces, or imbibed within the wall 1415 of sheath 1402, thereby protecting at least fifty percent of the surface area of one or more of its lumens, or any combination of these surfaces or areas, thus forming a shield against electromagnetic interference for the encased medical device.

The coatings of this invention may be used to coat a single conductor 133. Alternatively, or additionally, one may coat a multiple strand conductor. Thus, e.g., multiple strand conductors may be shielded by coating each strand separately, or by coating the multiple strand bundle. Thus, e.g., the multiple conductors within a single lead may be positioned concentrically to one another, or positioned spaced apart. Thus, e.g., the internally positioned conductors may be free to move, for example to rotate or translate, to for example control the motion of an active fixation electrode. By way of

illustration, the shielded conductors may be used in the lead designs shown in United States patents 6,289,251, 6,285,910, 6,192,280, 6,185,463, 6,178,355, 6,144,882, 6,119,042, 6,096,069, 6,066,166, 6,061,598, 6,040,369, 6,038,463, 6,026,567, 6,018,683, 6,016,436, 6,006,122, 5,999,858, 5,991,668, 5,968,087, 5,968,086, 5,967,977, 5,964,795, 5,957,970, 5,957,967, 5,957,965, 5,954,759, 5,948,015, 5,935,159, 5,897,585, 5,871,530, 5,871,528, 5,853,652, 5,796,044, 5,760,341, 5,702,437, 5,676,694, 5,584,873, 5,522,875, 5,423,881, 5,411,545, 5,354,327, 5,336,254, 5,336,253, 5,324,321, 5,303,704, 5,238,006, 5,217,027, 5,007,435, and the like. . The entire disclosure of each of these United States patents is hereby incorporated by reference into this specification.

In one embodiment, a conductor assembly comprised of a multifilar coiled conductor with a spiral configuration; is coated with one or more of the coating constructs of this invention. Reference to such a multifilar conductor is made, e.g., in United States patent 5,954,759, the entire disclosure of which is hereby incorporated by reference into this specification.

In one embodiment, one or more of such coating constructs are applied to a monofilar coiled conductor such as, e.g., the monofilar coiled conductor disclosed in United States patent 5,954,759. The entire disclosure of such United States patent is hereby incorporated by reference into this specification.

By way of further illustration, the one or more of the coating constructs may be used to coat one or more of the lead designs shown in United States patents numbers 6,289,251, 6,285,910, 6,192,280, 6,185,463, 6,178,355, 6,144,882, 6,119,042, 6,096,069, 6,066,166, 6,061,598, 6,040,369, 6,038,463, 6,026,567, 6,018,683, 6,016,436, 6,006,122, 5,999,858, 5,991,668, 5,968,087, 5,968,086, 5,967,977, 5,964,795, 5,957,970, 5,957,967,

5,957,965, 5,954,759, 5,948,015, 5,935,159, 5,897,585, 5,871,530, 5,871,528, 5,853,652, 5,796,044, 5,760,341, 5,702,437, 5,676,694, 5,584,873, 5,522,875, 5,423,881, 5,411,545, 5,354,327, 5,336,254, 5,336,253, 5,324,321; 5,303,704, 5,238,006, 5,217,027, and 5,007,435; the entire disclosure of each of these United States patents is hereby incorporated by reference into this specification. When so used, the modified assemblies thus produced are resistant to electromagnetic radiation.

In one embodiment, the coating constructs are used to coat a conductor assembly comprised of a multifilar conductor disposed inside a monofilar conductor. In another embodiment, the coating constructs are used to coat a conductor assembly wherein the multifilar conductor is disposed outside the monofilar conductor. In one aspect of this embodiment, only portions of the conductors are shielded.

By way of further illustration, a discontinuous shield is produced by a discontinuous coating of nanomagnetic particles and/or other coating constructs. This coating, e.g., may be intermittently discontinuous along its axial dimension, to provide for example, reduced exposure to an externally applied electromagnetic field. This coating may be, e.g., discontinuous at its proximal end, to provide for example, an electrically conductive surface for attachment to a medical device, such as an implantable pulse generator, a cardioversion-defibrillator pacemaker, an insulin pump, or other tissue or organ stimulating or sensing device. This coating, e.g., may be discontinuous along its distal end, to provide for example, an electrically conductive surface for contacting tissues or organs.

A discontinuous shield may be applied to non-wire conductors, such as for example a solid rod or other geometry conductor, used for example as an electrode for

transmitting and/or receiving electrical signals to/from tissues or organs. The discontinuous shield may be applied to any of the conductor or lead configurations described above and/or in United States patents 6,289,251, 6,285,910, 6,192,280, 6,185,463, 6,178,355, 6,144,882, 6,119,042, 6,096,069, 6,066,166, 6,061,598, 6,040,369, 6,038,463, 6,026,567, 6,018,683, 6,016,436, 6,006,122, 5,999,858, 5,991,668, 5,968,087, 5,968,086, 5,967,977, 5,964,795, 5,957,970, 5,957,967, 5,957,965, 5,954,759, 5,948,015, 5,935,159, 5,897,585, 5,871,530, 5,871,528, 5,853,652, 5,796,044, 5,760,341, 5,702,437, 5,676,694, 5,584,873, 5,522,875, 5,423,881, 5,411,545, 5,354,327, 5,336,254, 5,336,253, 5,324,321, 5,303,704, 5,238,006, 5,217,027, and 5,007,435; the entire disclosure of each which is hereby incorporated by reference into this specification. Because these devices are coated with nanomagnetic particles, they are resistant to electromagnetic radiation.

In one embodiment, one or more of the coating constructs are used to coat a multiple discontinuously shielded conductor assembly that is comprised of a multiplicity of shielded conductors each of which is coated discontinuously or continuously with nanomagnetic shielding. The centrally disposed conductor is preferably a pacing lead, and the other shielded conductors are preferably cardioversion defibrillation leads. In the embodiment depicted, the entire assembly is shielded with a layer of nanomagnetic material. As will be apparent, the use of discontinuous coating enables the multiple conductors to make electrical contact at one or more points along their axial dimension, to provide redundant electrical channels, in the event one channel should break. The discontinuous coating provides reduced exposure to externally applied electromagnetic fields. The discontinuous shield may be; intermittently discontinuous along its axial dimension, discontinuous at its proximal end, or discontinuous along its distal end. It is

to be understood that the discontinuous shield may be applied to any of the conductor or lead configurations described above.

By way of further illustration, one may use one or more of the coating constructs of this invention to coat a multiconductor lead connected to a catheter and a sheath. This assembly is similar to the assembly depicted in United States patent 6,178,355, the entire disclosure of which is hereby incorporated by reference into this specification, but differs therefrom in that the use of nanomagnetic particle shielding provides resistance to electromagnetic radiation.

Thus, by way of further illustration, one or more of the nanomagnetic coating constructs of this invention may be used in the lead designs shown in United States patents 6,285,910, 6,178,355, 6,119,042, 6,061,598, 6,018,683, 5,968,086, 5,957,967, 5,954,759, 5,871,530, 5,676,694; the entire disclosure of each of which is hereby incorporated by reference into this specification.

In one embodiment, the coating constructs are used to prepare a discontinuously shielded conductor similar to the assembly depicted in Figure 1 of United States patent 6,016,436. The entire disclosure of this patent is hereby incorporated by reference into this specification

In one embodiment, the coated substrate is a lead body that carries at its distal end an insulative electrode head which may be fabricated of a relatively rigid biocompatible plastic, such as a polyurethane; the electrode head carries an advanceable helical electrode. At its proximal end, the lead carries a trifurcated connector assembly provided with two connector pins each coupled to one of two elongated defibrillation electrode coils.

In one embodiment, a coated substrate is produced in which the coating is intermittently discontinuous along its axial dimension, to enable, for example, direct stimulation and sensing of tissues and organs, while providing, for example, reduced exposure to an externally applied electromagnetic field. Reference may be had, e.g., to the lead designs shown in United States patent numbers 6,289,251, 6,285,910, 6,119,042, 6,066,166, 6,061,598, 6,038,463, 6,018,683, 5,957,970, 5,957,967, 5,935,159, 5,871,530, 5,702,437, 5,676,694, 5,584,873, 5,336,254, 5,336,253, 5,238,006, 5,217,027, the entire disclosure of each of which is hereby incorporated by reference into this specification.

In one embodiment, the layer of nanomagnetic material is disposed on or within such medical device(s) and is comprised of electrical circuitry.

One may use the nanomagnetic coating(s) used to shield electronic components located within leads. One may use these coatings to shield medical leads with stranded conductors similar to those depicted in United States patent 6,026,567, the entire disclosure of which is hereby incorporated by reference into this specification. In the embodiment depicted therein, the assembly is comprised of a ring electrode a core 254, a distal insulative sleeve a conductor, a lumen, cross bores, a distal portion and a point adjacent to a shoulder (but see Figures 2, 3, and 4 of United States patent 6,026,567).

One may use the coatings constructs to coat a guidewire placed implantable lead with tip seal, such as that disclosed in United States patent 6,192,280 (the entire disclosure of which is hereby incorporated by reference into this specification). Such a lead is preferably comprised of an elongated insulative lead body, a laterally extending ridge, an internal conductive sleeve, a bore, a cup-shaped seal member, a plastic band, a controlled release device, an electrode, a distal tip, and a coiled conductor.

One may use the coating constructs to coat a catheter assembly that is similar to the catheter assembly disclosed in United States patent 6,144,882, the entire disclosure of which is hereby incorporated by reference into this specification.

By way of further illustration, one may use the coating constructs to coat conductor assemblies similar to those depicted in United States patent 5,935,159, the entire disclosure of which is hereby incorporated by reference into this specification. Thus, e.g., one may use the coatings to coat a medical electrical lead system having a torque transfer stylet assembly similar to the assembly depicted in United States patent 5,522,875, the entire disclosure of which is hereby incorporated by reference into this specification.

By way of yet further illustration, the coating constructs may be used to coat a stylet, similar to the stylet depicted in Figure 7A of United States patent 5,522,875, supra.

In one embodiment, the coating constructs form a film with a thickness of about 100 nanometers or larger, and they produce an article with a specified modulus of elasticity (Young's Modulus). As is known to those skilled in the art, the modulus of elasticity is the ratio of the stress acting on a substance to the strain produced. In general, and in this embodiment, the nanomagnetic particle coatings and films produced by the process of this invention have a tensile modulus of elasticity of at least about  $15 \times 10^6$  pounds per square inch.

The coating constructs may be used to coat a steerable wire. Steerable guide wires can be created, for example, by producing differential strain through tension wires electrically exciting piezoelectric elements. Each of these configurations is electrically conductive and susceptible to externally applied electromagnetic fields. The present

invention preferably coats these elements with a nanomagnetic coating shield to protect these elements during magnetic resonance imaging-guided installation.

The coating constructs of this invention may be used to coat a transesophageal medical lead similar to the device depicted in United States patent 5,967,977 (see Figure 1), the entire disclosure of which is hereby incorporated by reference into this specification.

The coating constructs of this invention may be used to coat a torque stylet used to activate a helix in a bent lead; see, e.g., United States Patent 5,522,875. The entire disclosure of this United States patent is hereby incorporated by reference into this specification.

The coating constructs of this invention may be used to coat a sheath, in order to shield uncoated conductors positioned within the sheath. Multiple concentrically positioned sheaths are also used to provide additional protection of uncoated conductors positioned within the sheaths. In one embodiment, this sheath is constructed of a tube impregnated with nanomagnetic particles, or a braided wire mesh coated with nanomagnetic particles. In one embodiment, an internally positioned conductor is free to move, e.g., free to rotate or translate. In another embodiment, the motion of the active fixation electrode is controlled. By way of illustration, the shielded conductors described in this specification may be used in the lead designs illustrated in United States Patents 6,289,251, 6,285,910, 6,192,280, 6,185,463, 6,178,355, 6,144,882, 6,119,042, 6,096,069, 6,066,166, 6,061,598, 6,040,369, 6,038,463, 6,026,567, 6,018,683, 6,016,436, 6,006,122, 5,999,858, 5,991,668, 5,968,087, 5,968,086, 5,967,977, 5,964,795, 5,957,970, 5,957,967, 5,957,965, 5,954,759, 5,948,015, 5,935,159, 5,897,585, 5,871,530, 5,871,528, 5,853,652,

5,796,044, 5,760,341, 5,702,437, 5,676,694, 5,584,873, 5,522,875, 5,423,881, 5,411,545, 5,354,327, 5,336,254, 5,336,253, 5,324,321, 5,303,704, 5,238,006, 5,217,027, and 5,007,435. The entire disclosure of each of these United States patent is hereby incorporated by reference into this specification.

Preparation of coatings comprised of nanoelectrical material

In this portion of the specification, coatings comprised of nanoelectrical material will be described. In accordance with one aspect of this invention, there is provided a nanoelectrical material with an average particle size of less than 100 nanometers, a surface area to volume ratio of from about 0.1 to about 0.05 1/nanometer, and a relative dielectric constant of less than about 1.5.

The nanoelectrical particles of aspect of the invention have an average particle size of less than about 100 nanometers. In one embodiment, such particles have an average particle size of less than about 50 nanometers. In yet another embodiment, such particles have an average particle size of less than about 10 nanometers.

The nanoelectrical particles of this invention have surface area to volume ratio of from about 0.1 to about 0.05 1/nanometer.

When the nanoelectrical particles of this invention are agglomerated into a cluster, or when they are deposited onto a substrate, the collection of particles preferably has a relative dielectric constant of less than about 1.5. In one embodiment, such relative dielectric constant is less than about 1.2.

In one embodiment, the nanoelectrical particles of this invention are preferably comprised of aluminum, magnesium, and nitrogen atoms. This embodiment is illustrated in Figure 24.

Figure 24 illustrates a phase diagram 2000 comprised of moieties A, B, and C. Moiety A is preferably selected from the group consisting of aluminum, copper, gold, silver, and mixtures thereof. It is preferred that the moiety A have a resistivity of from about 2 to about 100 microohm-centimeters. In one preferred embodiment, A is aluminum with a resistivity of about 2.824 microohm-centimeters. As will appear, other materials with resistivities within the desired range also may be used.

Referring again to Figure 24, C is selected from the group consisting of nitrogen and oxygen. It is preferred that C be nitrogen, and A is aluminum; and aluminum nitride is present as a phase in system.

Referring again to Figure 24, B is preferably a dopant that is present in a minor amount in the preferred aluminum nitride. In general, less than about 50 percent (by weight) of the B moiety is present, by total weight of the doped aluminum nitride. In one aspect of this embodiment, less than about 10 weight percent of the B moiety is present, by total weight of the doped aluminum nitride.

The B moiety may be, e.g., magnesium, zinc, tin, indium, gallium, niobium, zirconium, strontium, lanthanum, tungsten, mixtures thereof, and the like. In one embodiment, B is selected from the group consisting of magnesium, zinc, tin, and indium. In another especially preferred embodiment, the B moiety is magnesium.

Referring again to Figure 24, and when A is aluminum, B is magnesium, and C is nitrogen, it will be seen that regions 2002 and 2003 correspond to materials which have a low relative dielectric constant (less than about 1.5), and a high relative dielectric constant (greater than about 1.5), respectively.

Figure 25 is a schematic view of a coated substrate 2004 4 comprised of a substrate 2005 and a multiplicity of nanoelectrical particles 2006. In this embodiment, it is preferred that the nanoelectrical particles 2006 form a film with a thickness 2007 of from about 10 nanometers to about 2 micrometers and, more preferably, from about 100 nanometers to about 1 micrometer.

The description of the remaining Figures in this section of the specification is related to technology that is disclosed in United States patent 6,329,305, the entire disclosure of which is hereby incorporated by reference in to this specification.

Such United States patent 6,329,305, in its Column 1, refers to a patent application U.S.S.N. 09/503,225, for a “Method for Producing Piezoelectric Films...;” this patent application issued as United States patent 6,342,134 on January 29, 2003. The entire disclosure of such patent application and such patent is hereby incorporated by reference into this application.

Such United States patent 6,329,305, in its Column 1, also refers to pending patent application U.S.S.N. 09/145,323, filed on September 1, 1998, for a “Pulsed DC Reactive Sputtering Method...;” the entire disclosure of such pending application is also hereby incorporated by reference into this application.

Figure 26 is a sectional view of a sensor assembly 2010 comprised of a substrate 2012, a conductor 2014, a conductor 2016, a conductor 2018, a piezoelectric element 2020, a source of laser light 2060, a photodetector 2024, and heat conductors 2026 and 2028.

The substrate 2012, in one embodiment, is preferably pure silicon, which, in one embodiment, is single crystal silicon. Processes for making and using single crystal

silicon structures are well known. Reference may be had, e.g., to United States patents 6,284,309 (epitaxial silicon waver), 6,136,630 (single crystal silicon), 5,912,068 (single crystal silicon), 5,818,100 (single crystal silicon), 5,646,073 (single crystal silicon), and the like. The entire disclosure of each of these United States patents is hereby incorporated by reference into this specification. The entire disclosure of this United States patent is hereby incorporated by reference into this specification.

Referring again to Figure 26, and in the preferred embodiment depicted therein, the substrate 2012 generally has a thickness of from about 1 to about 2 millimeters.

In one embodiment, the single-crystal silicon substrate 2012 preferably has a <100> orientation. As is known to those skilled in the art, <100> refers to the lattice orientation of the silicon (see, e.g., Column 5 of United States patent 6,329,305). Reference also may be had to a text by S.M. Sze entitled "Physics of Semiconductor Devices," 2d Edition (Wiley-Interscience, New York, New York, 1981). At page 386 of this text, Table 1 indicates that there are three silicon crystal plane orientations, <111>, <110>, and <100>. The <100> orientation is preferred for one embodiment, the <110> orientation is preferred for a second embodiment, and the <111> orientation is preferred for a third embodiment. In any case, the single crystal silicon substrate 12 has only one of such orientations.

Referring again to Figure 26, aluminum conductors 2014 and 2016 are grown near the periphery of substrate 2012. The structure depicted in Figure 26 may be produced by growing an entire layer of aluminum and then etching away a portion thereof.

Referring to Figure 27A, an aluminum layer 2013 may be grown on substrate 2012, preferably by conventional sputtering techniques. Reference may be had, e.g., to United States patents 5,835,273 (deposition of an aluminum mirror), 5,711,858 (deposition of aluminum alloy film), 4,976,839 (aluminum electrode), and the like. The entire disclosure of each of these United States patents is hereby incorporated by reference into this specification.

One may deposit either aluminum or an aluminum alloy, provided that such aluminum material preferably has a certain conductivity. It is preferred that the aluminum conductor 2014 have a resistivity of less than about 3 microohms-centimeter. Conductor 2016 should have a resistivity of at least 1.5 times as great as the resistivity of conductor 2014, and such resistivity is generally less than about 5 microohms-centimeters.

One can vary the resistivity of elements 2014 and 2016 during deposition thereof by preferentially providing a high oxygen content near point 2015 so that conductor 2016, after it has been formed, will contain more oxide material and have a higher resistivity.

Referring again to Figure 27A, a layer 2013 of aluminum may be deposited onto substrate 2012 by reactive sputtering, as described hereinabove; and, during such deposition, selective reaction with oxygen (or other gases) may be caused to occur at specified points (such as point 2015) of the aluminum layer being deposited. Thereafter, after the solid layer 2013 has been deposited, it can be preferentially etched away.

In one embodiment, and referring again to Figure 27B, a mask (indicated in dotted line outline) may be deposited onto the layer 2013, and thereafter the unmasked

deposited aluminum may be etched away with conventional aluminum etching techniques.

Thus, e.g., one may etch the unmasked area with sputtered with argon or hydrogen or oxygen gas, using conventional sputtering technology; as is known to those skilled in the art, etching is the opposite of deposition. Reference may be had, e.g., to United States patents 5,851,364, 5,685,960, 6,222,271, 6,194,783, and the like. The entire disclosure of each of these United States patents is hereby incorporated by reference into this specification.

After the conductors 2014 and 2016 have been integrally formed with substrate 2012, a piezoelectric material 2020 is deposited onto the substrate 2012/conductors/2014-2016 assembly by sputtering. In one preferred embodiment, the piezoelectric material 2020 is piezoelectric aluminum nitride.

In one aspect of this embodiment, after conductors 2014 and 2016 have been formed by sputtering/etching, aluminum nitride is preferably formed by sputtering an aluminum target 2030 with nitrogen gas directed in the direction of arrows 2032 and/or 2034.

In one embodiment, the aluminum nitride layer 2020 (see Figure 26) has a preferred <002> orientation. Means for producing aluminum nitride with such <002> orientation are well known to those skilled in the art. Reference may be had, e.g., to United States patent 6,329,305, which, at Column 1, refers to “An example of an advantageous film orientation is <002> of AlN perpendicular to the substrate.” This patent claims: “A method for fabricating an electronic device having a piezoelectric material deposited on at least one metal layer, the method comprising depositing the at

least one metal layer on a substrate and depositing the piezoelectric material on the metal layer, wherein the texture of the piezoelectric material is determined by controlling the surface roughness of the metal layer.” The entire disclosure of this United States patent is hereby incorporated by reference into this specification.

Figure 28 is a schematic representation of a film orientation <002> of aluminum nitride, with respect to substrate 2012 and/or film plane 2038. Referring to Figure 26, and in the preferred embodiment depicted therein, it will be seen that columnized growths 2021 preferably form such aluminum nitride 2020. These columnar growths 2021 are substantially perpendicular to the substrate 2012. Reference may be had, e.g., to R.F. Bunshah’s “Deposition Technologies for Films and Coatings” (Noyes Publications, Park Ridge, New Jersey, 1982). At page 131 of such text, columnar grains in a condensate are shown in Figure 4.36.

Referring again to Figure 26, the <002> aluminum nitride is deposited up to level 2036 so that layer 2020 has a thickness of about 1 micron. Thereafter, layers 2026 and 2028 are deposited onto the assembly by sputtering.

These layers 2026 and 2028 also preferably consist essentially of aluminum nitride, but they preferably are not piezoelectric. One may obtain such non-piezoelectric properties (or lack thereof) by conventional sputtering techniques in which the aluminum nitride is deposited but no alignment thereof is induced.

Thus, e.g., in the embodiment depicted in Figure 26 one may dispose a heater 2040 beneath the substrate 2012 and operate such heater when one is depositing the aluminum nitride material with the <002> orientation (with respect to substrate 2012 and/or film plane 2038) and the piezoelectric properties. Thereafter, one may turn the

heater 2040 off while depositing the aluminum nitride layers 2026/2028, neither of which has piezoelectric properties or the <002> orientation with respect to film planes 2042/2044.

However, although the layers 2026 and 2028 do not have piezoelectric properties, they do have certain heat conductivity properties. It is preferred that each of layers 2026 and 2028 have a heat conductance of about 2 Watt/degrees Centigrade/centimeter and a resistivity of about  $1 \times 10^{16}$  ohm-centimeter. As will be apparent, each of layers 2026 and 2028 are heat conductors.

Figure 29 is a schematic of a preferred process similar to that depicted in Figure 26. Referring to Figure 26, in the manner described elsewhere in this specification, a layer 2041 of aluminum material is deposited by sputtering (also see Figure 27A). Thereafter, in the manner depicted in Figure 27B, portions 2046 and 2048 are etched away by reactive sputtering to leave the integrally formed conductive layer 2018. Thereafter, another layer of aluminum nitride is deposited, as is illustrated in Figure 30.

Referring to Figure 30, a layer of aluminum nitride 2050 is deposited by sputtering. This is preferably done only after conductor 2052 is deposited in the manner described hereinabove; and, after it has been done, conductor 2054 is formed in the manner described hereinabove.

The aluminum nitride material that forms layer 2050 preferably has a direct energy band gap of 6.2 electron volts, a heat conductance of about 2 Watt/degrees-Centigrade/centimeter and a resistivity of about  $1 \times 10^{16}$  ohm-centimeter. This material also is substantially pure aluminum nitride; and, consequently, it functions as a laser material after it has been formed into the structure depicted in Figure 30, wherein the

section that is shown as being crossed-out is etched away in the manner described elsewhere.

In this embodiment, the final desired structure is depicted in Figure 31. In another embodiment, shown in Figure 26, a photodetector layer 2024 is deposited with material which, in one aspect, is substantially the same as material 2022. In this aspect, both structure 2022 and 2024 are preferably simultaneously formed by etching. In this aspect, two aluminum conductors (not shown) are formed in the same manner as conductors 2052 and 2054 (see Figure 31), but are integrally connected to device 2024.

Referring to Figure 31, when the laser device 2060 receives electrical current via lines 2061 and 2063, laser light is emitted in the direction of arrow 2070.

Referring to Figure 26, when photonic energy 2071 impacts photodetector 2024, the electrical properties of photodetector 2024 are changed, whereby a signal is produced from such sensor.

#### A coated substrate with a dense coating

Figure 32A and 32B are sectional and top views, respectively, of a coated substrate 2100 assembly comprised of a substrate 2102 and, disposed therein, a coating 2104.

In the embodiment depicted, the coating 2104 has a thickness 2106 of from about 400 to about 2,000 nanometers and, in one embodiment, has a thickness of from about 600 to about 1200 nanometers.

Referring again to Figures 32A and 32B, it will be seen that coating 2104 has a morphological density of at least about 98 percent. As is known to those skilled in the art, the morphological density of a coating is a function of the ratio of the dense coating

material on its surface to the pores on its surface; and it is usually measured by scanning electron microscopy.

By way of illustration, published United States patent application US 2003/0102222A1 contains a Figure 3A that is a scanning electron microscope (SEM) image of a coating of "long" single-walled carbon nanotubes on a substrate. Referring to this SEM image, it will be seen that the white areas are the areas of the coating where pores occur.

The technique of making morphological density measurements also is described, e.g., in a M.S. thesis by Raymond Lewis entitled "Process study of the atmospheric RF plasma deposition system for oxide coatings" that was deposited in the Scholes Library of Alfred University, Alfred, New York in 1999 (call Number TP2 a75 1999 vol 1., no. 1.).

Figures 32A and 32B schematically illustrate the porosity of the side 2107 of coating 2104, and the top 2109 of the coating 2104. The SEM image depicted shows two pores 2108 and 2110 in the cross-sectional area 2107, and it also shows two pores 2212 and 2114 in the top 2109. As will be apparent, the SEM image can be divided into a matrix whose adjacent lines 2116/2120, and adjacent lines 2118/2122 define square portion with a surface area of 100 square nanometers (10 nanometers x 10 nanometers). Each such square portion that contains a porous area is counted, as is each such square portion that contains a dense area. The ratio of dense areas/porous areas, x 100, is preferably at least 98.. Put another way, the morphological density of the coating 2104 is at least 98 percent. In one embodiment, the morphological density of the coating 2104 is at least about 99 percent. In another embodiment, the morphological density of the coating 2104 is at least about 99.5 percent.

One may obtain such high morphological densities by atomic size deposition, i.e., the particles sizes deposited on the substrate are atomic scale. The atomic scale particles thus deposited often interact with each other to form nano-sized moieties that are less than 100 nanometers in size.

In one embodiment, the coating 2104 (see Figures 32A and 32B) has an average surface roughness of less than about 100 nanometers and, more preferably, less than about 10 nanometers. As is known to those skilled in the art, the average surface roughness of a thin film is preferably measured by an atomic force microscope (AFM). Reference may be had, e.g., to United States patents 5,420,796 (method of inspecting planarity of wafer surface), 6,610,004, 6,140,014, 6,548,139, 6,383,404, 6,586,322, 5,832,834, and 6,342,277. The entire disclosure of each of these United States patents is hereby incorporated by reference into this specification.

Alternatively, or additionally, one may measure surface roughness by a laser interference technique. This technique is well known. Reference may be had, e.g., to United States patents 6,285,456 (dimension measurement using both coherent and white light interferometers), 6,136,410, 5,843,232 (measuring deposit thickness), 4,151,654 (device for measuring axially symmetric aspherics), and the like. The entire disclosure of these United States patents are hereby incorporated by reference into this specification.

In one embodiment, the coated substrate of this invention has durable magnetic properties that do not vary upon extended exposure to a saline solution. If the magnetic moment of a coated substrate is measured at "time zero" (i.e., prior to the time it has been exposed to a saline solution), and then the coated substrate is then immersed in a saline solution comprised of 7.0 mole percent of sodium chloride and 93 mole percent of water,

and if the substrate/saline solution is maintained at atmospheric pressure and at temperature of 98.6 degrees Fahrenheit for 6 months, the coated substrate, upon removal from the saline solution and drying, will be found to have a magnetic moment that is within plus or minus 5 percent of its magnetic moment at time zero.

In another embodiment, the coated substrate of this invention has durable mechanical properties when tested by the saline immersion test described above.

In one embodiment, the coating 2104 is biocompatible with biological organisms. As used herein, the term biocompatible refers to a coating whose chemical composition does not change substantially upon exposure to biological fluids. Thus, when the coating 2104 is immersed in a 7.0 mole percent saline solution for 6 months maintained at a temperature of 98.6 degrees Fahrenheit, its chemical composition (as measured by, e.g., energy dispersive X-ray analysis [EDS, or EDAX]) is substantially identical to its chemical composition at "time zero."

#### A preferred process of the invention

In one embodiment of the invention, best illustrated in Figure 11, a coated stent is imaged by an MRI imaging process.

In the first step of this process, the coated stent described by reference to Figure 11 is contacted with the radio-frequency, direct current, and gradient fields normally associated with MRI imaging processes; these fields are discussed elsewhere in this specification. They are depicted as an MRI imaging signal 440 in Figure 11.

In the second step of this process, the MRI imaging signal 440 penetrates the coated stent 400 and interacts with material disposed on the inside of such stent, such as,

e.g., plaque particles 430 and 432. This interaction produces a signal best depicted as arrow 441 in Figure 11.

In one embodiment, the signal 440 is substantially unaffected by its passage through the coated stent 400. Thus, in this embodiment, the radio-frequency field that is disposed on the outside of the coated stent 400 is substantially the same as the radio-frequency field that passes through and is disposed on the inside of the coated stent 400.

By comparison, when the stent (not shown) is not coated with the coatings of this invention, the characteristics of the signal 440 are substantially varied by its passage through the uncoated stent. Thus, with such uncoated stent, the radio-frequency signal that is disposed on the outside of the stent (not shown) differs substantially from the radio-frequency field inside of the uncoated stent (not shown). In some cases, because of substrate effects, substantially none of such radio-frequency signal passes through the uncoated stent (not shown).

In the third step of this process, and in one embodiment thereof, the MRI field(s) interact with material disposed on the inside of coated stent 400 such as, e.g., plaque particles 430 and 432. This interaction produces a signal 441 by means well known to those in the MRI imaging art.

In the fourth step of the preferred process of this invention, the signal 441 passes back through the coated stent 400 in a manner such that it is substantially unaffected by the coated stent 400. Thus, in this embodiment, the radio-frequency field that is disposed on the inside of the coated stent 400 is substantially the same as the radio-frequency field that passes through and is disposed on the outside of the coated stent 400.

By comparison, when the stent (not shown) is not coated with the coatings of this invention, the characteristics of the signal 441 are substantially varied by its passage through the uncoated stent. Thus, with such uncoated stent, the radio-frequency signal that is disposed on the inside of the stent (not shown) differs substantially from the radio-frequency field outside of the uncoated stent (not shown). In some cases, because of substrate effects, substantially none of such signal 441 passes through the uncoated stent (not shown).

Another preferred process of the invention

Figures 33A, 33B, and 33C illustrate another preferred process of the invention in which a stent 2200 may be imaged with an MRI imaging process. In the embodiment depicted in Figure 33A, the stent 2200 is comprised of plaque 2202 disposed inside the inside wall 2204 of the stent 2200.

Figure 33B illustrates three images produced from the imaging of stent 2200, depending upon the orientation of such stent 2200 in relation to the MRI imaging apparatus reference line (not shown). With a first orientation, an image 2206 is produced. With a second orientation, an image 2208 is produced. With a third orientation, an image 2210 is produced.

By comparison, Figure 33C illustrates the images obtained when the stent 2200 has the nanomagnetic coating of this invention disposed about it. Thus, when the coated stent 400 of Figure 11 is imaged, the images 2212, 2214, and 2216 are obtained.

The images 2212, 2214, and 2216 are obtained when the coated stent 400 is at the orientations of the uncoated stent 2200 the produced images 2206, 2208, and 2210,

respectively. However, as will be noted, despite the variation in orientations, one obtains the same image with the coated stent 400.

Thus, e.g., the image 2218 of the coated stent will be identical regardless of how such coated stent is oriented vis-a-vis the MRI imaging apparatus reference line (not shown). Thus, e.g., the image 2220 of the plaque particles will be the same regardless of how such coated stent is oriented vis-a-vis the MRI imaging apparatus reference line (not shown).

Consequently, in this embodiment of the invention, one may utilize a nanomagnetic coating that, when imaged with the MRI imaging apparatus, will provide a distinctive and reproducible imaging response regardless of the orientation of the stent.

Figures 34A and 34B illustrate a hydrophobic coating 2300 and a hydrophilic coating 2301 that may be produced by the process of this invention.

As is known to those skilled in the art, a hydrophobic material is antagonistic to water and incapable of dissolving in water. A hydrophobic surface is illustrated in Figure 34A.

Referring to Figure 34A, it will be seen that a coating 2300 is deposited onto substrate 2302. In the embodiment depicted, the coating 2300 an average surface roughness of less than about 1 nanometer. Inasmuch as the average water droplet has a minimum cross-sectional dimension of at least about 3 nanometers, the water droplets 2304 will tend not to bond to the coated surface 2306 which, thus, is hydrophobic with regard to such water droplets.

One may vary the average surface roughness of coated surface 2306 by varying the pressure used in the sputtering process described elsewhere in this specification. In general, the higher the gas pressure used, the rougher the surface.

Figure 34B illustrates water droplets 2308 between surface features 2310 of coated surface 2312. In this embodiment, because the surface features 2310 are spaced from each other by a distance of at least about 10 nanometers, the water droplets 2308 have an opportunity to bond to the surface 2312 which, in this embodiment, is hydrophilic.

The bond formed between the substrate and the coating

Applicants believe that, in at least one preferred embodiment of the process of their invention, the particles in their coating diffuse into the substrate being coated to form a interfacial diffusion layer. This structure is best illustrated in Figure 35 which, as will be apparent, is not drawn to scale.

Referring to Figure 35, the coated assembly 3000 is preferably comprised of a coating 3002 disposed on a substrate 3004. The coating 3002 preferably has a thickness 3008 of at least about 150 nanometers.

The interlayer 3006, by comparison, has a thickness of 3010 of less than about 10 nanometers and, preferably, less than about 5 nanometers. In one embodiment, the thickness of interlayer 3010 is less than about 2 nanometers.

The interlayer 3006 is preferably comprised of a heterogeneous mixture of atoms from the substrate 3004 and the coating 3002. It is preferred that at least 10 mole percent of the atoms from the coating 3002 are present in the interlayer 3006, and that at least 10 mole percent of the atoms from the substrate 3004 are in the interlayer 3006. It is more

preferred that from about 40 to about 60 mole percent of the atoms from each of the coating and the substrate be present in the interlayer 3006, it being apparent that more atoms from the coating will be present in that portion 3012 of the interlayer closest to the coating, and more atoms from the substrate will be present in that portion 3014 closest to the substrate.

In one embodiment, the substrate 3004 will consist essentially of niobium atoms with from about 0 to about 2 molar percent of zirconium atoms present. In another embodiment, the substrate 3004 will comprise nickel atoms and titanium atoms . In yet another embodiment, the substrate will comprise tantalum atoms, or titanium atoms.

The coating may comprise any of the A, B, and/or C atoms described hereinabove. By way of way of illustration, the coating may comprise aluminum atoms and oxygen atoms (in the form of aluminum oxide), iridium atoms and oxygen atoms (in the form of iridium oxide), etc.

While the present invention has been described by reference to the above-mentioned embodiments, certain modifications and variations will be evident to those of ordinary skill in the art.